

3 1761 11848432 8







Digitized by the Internet Archive  
in 2023 with funding from  
University of Toronto

<https://archive.org/details/31761118484328>





CA20N  
21  
-1988  
PO11 v.1

67

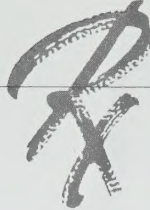
# *Prescriptions for Health Recommandations pour la santé*

Report  
of the  
Pharmaceutical  
Inquiry  
of Ontario

Rapport  
du Comité  
d'enquête  
de l'Ontario  
sur les produits  
pharmaceutiques







## **Prescriptions for Health**

**Report of the  
Pharmaceutical  
Inquiry  
of Ontario**

## **Recommandations pour la santé**

**Rapport du Comité  
d'enquête de l'Ontario  
sur les produits  
pharmaceutiques**

**Chairman:/Président:**

Frederick H. Lowy

**Committee:/  
Membres du Comité:**

Martha Jordan  
Michael Gordon  
Richard Moulton  
Reva Spunt  
Jake Thiessen  
Donald Webster  
William Wensley

**Executive Director:/  
Directrice générale:**

Wendy Kennedy

**Research Director:/  
Directeur de recherche:**

J. Ivan Williams

**Research Assistant:/  
Adjointe de recherche:**

Michelle Chibba

**Administrative Assistant:/  
Adjointe administrative:**

D. Betty Reid





# **PHARMACEUTICAL**

## **INQUIRY OF ONTARIO**

July, 1990

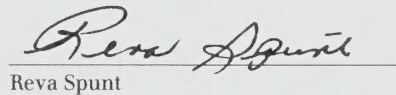
The Honorable Elinor Caplan  
Minister of Health  
Queen's Park  
Toronto, Ontario

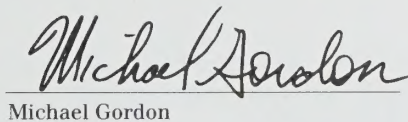
Dear Minister:

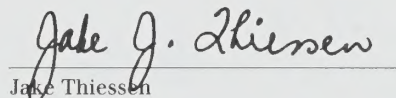
By Order-in-Council dated May 26, 1988, pursuant to section 9 of the Ministry of Health Act, R.S.O. 180, chapter 280, we were appointed to examine all matters pertaining to the acquisition, distribution, prescribing, dispensing and use of prescription drugs in Ontario. We have completed our Inquiry and hereby respectfully submit our findings and recommendations.


Yours very truly,

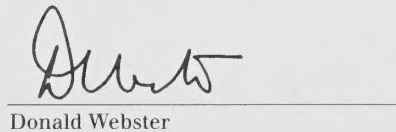
  
Frederick Lowy, Chairman

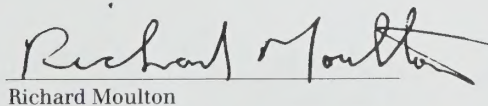
  
Reva Spunt

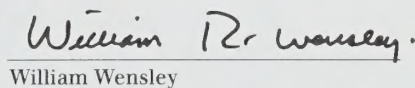
  
Michael Gordon

  
Jake Thiessen

  
Martha Jordan

  
Donald Webster

  
Richard Moulton

  
William Wensley

**D'ENQUÊTE DE L'ONTARIO  
SUR LES PRODUITS  
PHARMACEUTIQUES**

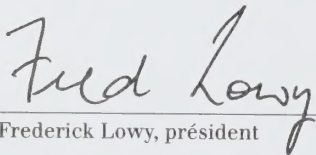
Juillet 1990

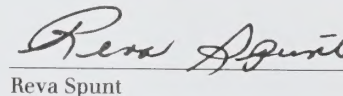
L'honorable Elinor Caplan  
Ministre de la Santé  
Queen's Park  
Toronto (Ontario)

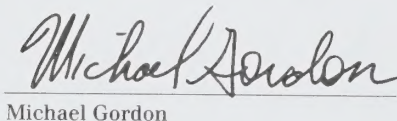
Madame la ministre,

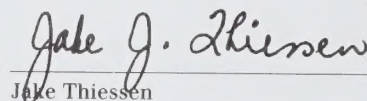
En vertu d'un décret daté du 26 mai 1988, par l'application de l'article 9 de la Loi sur le ministère de la Santé, L.R.O. 180, chapitre 280, nous avons été nommés pour étudier toutes les questions afférentes à l'acquisition, la distribution, la prescription, la délivrance et l'utilisation des produits de prescription en Ontario. Nous avons terminé notre enquête et vous soumettons respectueusement nos conclusions et recommandations, par les présentes.

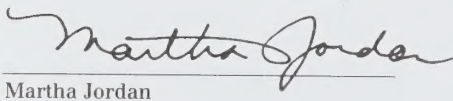
Nous vous prions d'agréer, Madame la ministre, l'expression de nos sentiments les plus respectueux.

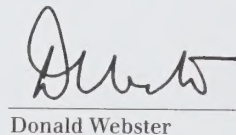
  
Frederick Lowy, président

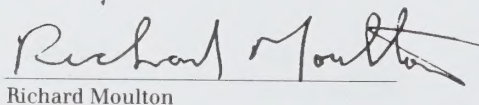
  
Reva Spunt

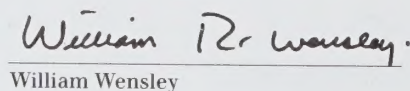
  
Michael Gordon

  
Jake Thiessen

  
Martha Jordan

  
Donald Webster

  
Richard Moulton

  
William Wensley





## Acknowledgements

It is with much gratitude that I acknowledge the contributions of the people who made the work of the Inquiry possible.

My colleagues on the Committee of Inquiry devoted themselves to the task with enthusiasm. They skilfully brought to bear diverse backgrounds and perspectives on the variety of problems encompassed by our broad mandate.

The Committee had the good fortune to work with an exceptionally able staff. Ms. Wendy Kennedy, the Inquiry's executive director, successfully applied her rich background in law, management and the pharmaceutical industry and is largely responsible for the smooth conduct of the work. She received high quality assistance from Ms. Michelle Chibba whose research skills served the Committee well. Professor Jack Williams, our distinguished research director, coordinated the external consultants and undertook the daunting task of collecting relevant background material. The Inquiry was able to count on first rate clerical support from Ms. Betty Reid, assisted from time to time by Ms. Cathy McPherson and Ms. Jenifer Rush.

The help of our external consultants is also acknowledged with thanks. They are professors R. Cockerill, J. Frank, J. Hurley, P. Gorecki, P. Williams and Ms. C. Hardt-Zeldin, whose findings are published in Volume II of this report and professors H. Eastman and J. Gordon, whose valuable advice we drew on as needed.

We are all immensely grateful to Ms. Mary-Catherine Lindberg, assistant Deputy Minister, her predecessor, Dr. Dennis Psutka and the staff of the drug programs branch of the Ministry of Health, especially Mr. Gordon Ventura. They extended us full cooperation and greatly facilitated the work of the Inquiry.

Finally, I record my thanks to Mr. Joerg Ostermann who so ably supervised the editing of this report and the communications and information branch of the Ministry which was responsible for its production.

To all I express my appreciation.

  
Frederick H. Lowy  
Chairman







## Executive Summary

### Report of the Pharmaceutical Inquiry of Ontario

*The Pharmaceutical Inquiry of Ontario was established to examine the role and influence of the government of Ontario with respect to prescription drugs. Although a major reason for its establishment was concern over the steep rise in the cost of government drug programs—about 20 per cent annually and 508 per cent over the past decade—the Inquiry did not regard cost containment as its only, or even primary, task.*

*The report contains 147 recommendations. Most of these are directed to the government of Ontario which commissioned the Inquiry, but some require consideration by professional associations, the statutory bodies that regulate the health professions in Ontario, the five university health science centres, pharmaceutical manufacturers and distributors, and the public.*

*We are convinced that these recommendations, when implemented, will contribute toward the achievement of accessible, higher quality treatment for those Ontarians who need prescription drugs, and will help eliminate unnecessary public expenditure.*

*The committee reached several major conclusions:*

#### A

Ontarians generally receive excellent treatment involving prescription drugs. For the most part, pharmaceutical products are safe, effective and appropriately prescribed, dispensed and used. Prescription drugs are generally available promptly. They are affordable for most Ontario residents; about 1.5 million people (16 per cent of the population), including all seniors and persons receiving social assistance, qualify for government-financed drug programs. In addition, approximately 6.7 million individuals (70 per cent) have access to private insurance plans that cover most or all drug costs; many other Ontario residents pay for drugs out-of-pocket.

Since prescription drugs are an important component of modern health care, the Committee found all this reassuring.

## B

However, even good programs can be improved. The Committee identified a number of problem areas that require attention and to which the recommendations are directed.

Among these are the following:

- Some pharmaceutical products listed in the Ontario Drug Benefit plan formulary (the costs of which are reimbursed with public funds) are sub-optimally effective and/or have unfavourable benefit/risk ratios.
- Physicians are not as well prepared educationally for prescribing the thousands of drug products available as they might be, especially with respect to the elderly. The continuing education of physicians with respect to the use of new drug products requires improvement.
- Pharmacists are not meeting their full professional potential as members of the health care team.
- Some Ontarians who need prescription drugs do not have ready access to them; they do not qualify for government programs because they are under 65 and are not receiving social assistance and they cannot purchase adequate private insurance. The two groups most at risk are those who do not have insurance through the workplace but have low incomes (the “working poor”) and people with extraordinary drug costs due to severe chronic disease or disability. An estimated 600,000 to 700,000 individuals fall into one of these groups and do not have adequate access to needed drugs.

## C

Canadian governments must continue to assume major responsibility in the prescription drug field; specifically, they must ensure that drugs are effective and affordable. Coordination among federal and provincial ministries is less than optimal. There is no national policy regarding drug interchangeability and the process of approval and licensing of drugs is more complicated and time consuming than it needs to be. Although provincial government policies have encouraged generic drug product use, prescription drug costs have not been well contained.

Recommendations are made to address these and other problem areas identified by the Inquiry.

*A chapter-by-chapter summary of the report follows.*



## ***Chapter I Introduction***

The Inquiry recognized that the broad terms of reference could not be investigated in depth during the 19 month mandate, later extended to 22 months. The decision was taken to focus on the three principal objectives of our mandate: to improve the quality of pharmacotherapy in Ontario, to ensure appropriate access to necessary medications for all Ontarians; and to contain prescription drug costs which have been rising steeply.

Numerous groups and individuals contributed advice, assistance and information—some of it unsolicited, most of it through public hearings or as a direct response to a specific request—during the course of the inquiry's work. The inquiry also reviewed government drug programs, previous studies and reports and relevant legislation and commissioned research projects to provide supplementary information.

Four interim progress reports were released to the Minister of Health; these are presented in the appropriate context within this report.

## ***Chapter II Objectives of the Inquiry —Optimal Drug Therapy***

It is the basis of the Inquiry that Ontarians should benefit from a system that will assure optimal drug treatment which is appropriate, accessible, affordable and conserves scarce resources. Prescription drugs play roles of varying importance in health care; a major role in the treatment of disease and in the relief of symptoms, and a much smaller role in health promotion, illness prevention, rehabilitation and in response to life stress. There is no place for prescription drugs as recreational agents.

The Committee examined the appropriate role of governments and determined that while the professions and consumers themselves have important parts to play with regard to prescribing, dispensing and use of prescription drugs, the main responsibility with respect to assuring drug quality, appropriate access and affordability rests with government, with the Ontario Ministry of Health playing the leading role in each case.

## ***Chapter III Prescription Drug Programs in Ontario***

The history of prescription drug programs in Ontario is reviewed in this chapter.

Public funding for prescribed drugs in Ontario began with the federal Hospital Insurance and Diagnostic Services Act, which came into effect in 1958 (Ontario joined in 1959.) Under the program, insured medical services in hospitals included prescribed drugs. Over the years that followed, a number of programs by municipal, provincial and federal governments extended various health programs to people requiring social assistance. Private health insurance plans also began to assist with drug costs.

The 1964 Hall Royal Commission laid the foundations for the Canada Health Act (1968) upon which our health care system is based.

The Hall Commission recommended that outpatient prescription drugs, as well as in-hospital drugs, be included as a publicly insured benefit and a \$1 contributory payment for most prescriptions was proposed. However, contrary to this recommendation, the national health insurance program established by the Canada Health Act did not include outpatient prescription drugs.

During the late 1960s, the provincial government took steps to facilitate the prescribing of generic drug products. Also during this period, the Drug Quality and Therapeutics Committee (DQTC), an independent advisory group to the Minister of Health which assured the quality of Ontario drug products was struck, and the CDI, or comparative drug index, which evolved into the Ontario Drug Benefit (ODB) formulary, was established.

In 1974, the provincial government introduced the ODB plan, initially to provide free drugs to senior citizens eligible for guaranteed income supplement benefits and to recipients of other government social assistance programs. A year later, the program was extended to all Ontario residents aged 65 and over. Eligible benefits were listed in the formulary, which set price limits for multi-source drugs by publishing the amount the government would reimburse for the drug product in question. The DQTC recommended drugs to be admitted to the formulary, assured the quality of the drugs and determined which were interchangeable.

Bills 54 and 55, respectively the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act, were put into force at the end of 1986. Bill 54 gave the government the authority to manage the ODB program effectively while Bill 55 was to ensure that consumers get the information needed to make informed, economical drug purchases.

From 1978 to 1988, the ODB plan experienced an average annual increase of 20.4 per cent, making it one of the fastest growing health care programs over the period; the total paid for the program in 1988-89 was \$637.9 million.

## ***Chapter IV The Formulary and the DQTC***

The Inquiry believes that a number of shortcomings are associated with the formulary as it exists today: it does not contain information regarding common doses; it does not advise treatment strategies; it is said not to be user friendly. Most important, it is not used by most prescribers. The Committee considered two options: elimination or modification of the formulary, and ultimately opted for the latter alternative.

To effect the desired changes, the Committee has made recommendations directed to: creation of a new formulary; a review of all products currently listed with respect to efficacy, safety, equivalence and cost; the development of categories for general and restricted use; not requiring a manufacturers' submission in order to list drugs; regular reevaluation monitoring to increase prescribers accountability; the possible reimbursement of nonformulary drugs; listings for nonconventional dosage forms, mechanisms to promote generic prescribing and a continuous system of product review.

The DQTC determines which drugs should be contained in the formulary, under which categories, and which products are interchangeable. It is composed of physicians, pharmacists and scientists who have the recognized expertise to advise the Minister, aided by external consultants who furnish reviews and advice. Some submissions to the Inquiry advocated abolishing the DQTC and although alternatives can be envisioned, there is no compelling reason which dictates a change. However, the Committee does recommend an expanded mandate to permit more effective evaluation of cost factors and the impact of formulary changes, and

more communication between health care professionals and the DQTC.

With regard to “special authorization” (SA) products—drugs not on the regular formulary but considered necessary to good health in particular instances—the Committee recommended in its interim report of December, 1988 that the SA program be discontinued and all drugs authorized under the ODB program be approved by the DQTC. Among a number of other recommendations in this area, the Inquiry also recommends that the formulary contain limited use and regular use categories and the DQTC establish a mechanism for quick review of drugs which represent major therapeutic advances.

On the subject of drug interchangeability, the Committee recommends that the present policy which promotes generic drug substitution should be continued; pharmacists should continue to be reimbursed only at the price of the lowest equivalent drug product, and should refill prescriptions with the product originally dispensed when the price is equivalent; they should be reimbursed for a “no-substitution” prescription of a higher priced product only when there is an approved reason for this; the patient should have the option of paying the difference in price in the case of “no-substitution” prescriptions; special arrangements should be made if the patient cannot tolerate the lowest price product; pharmacists should inform the patient and prescriber when substitution has occurred; and manufacturers should publicize appropriate information when a new generic first comes into general use.

## *Chapter V Acquisition of Drugs*

The pharmaceutical industry is divided into two main groups: innovative and generic manufacturers. The innovative, or brand-name segment in Canada falls largely to the multinationals, mainly through manufacturing and distribution subsidiaries. Compulsory licensing legislation is responsible for the growth of the generic segment which is comprised largely of Canadian owned manufacturers. Overall, the industry is highly profitable and growing more quickly in Canada than it is world-wide.

Through the formulary, the province establishes the “best available price”—or BAP—the lowest price for which that product is available in Canada for sale in Ontario. To be legally marketed in Canada, a drug must be approved for sale by the federal government’s Health Protection Branch (HPB); obtaining this approval can be a time consuming process. The Ontario government, through the DQTC, determines whether two or more brands are bioequivalent and assumes legal liability for pharmacists’ dispensing the least expensive equivalent brand. To streamline this process, the Inquiry recommends that Ontario take the lead in promoting a Canada-wide interchangeability policy.

The Committee also recommends a maximum level for the introductory price of new generics; maintenance of the BAP concept; a formula to roll back drug prices and limit increases to the CPI; a limit to future price increases; an auditing mechanism to retroactively adjust the reimbursement of some pharmacists; and a disclosure requirement on the part of pharmacists in cases where consumers present non-ODB prescriptions.



This section also deals with hospital purchasing plans and proposes that the concept of a limited formulary be supported and facilitated for smaller hospitals, nursing homes and homes for the aged and in community practice.

### ***Chapter VI Distribution of Drugs***

There are some major problems with distribution of drugs in Ontario involving the changing relationships between retail pharmacies and wholesalers due to

- direct group buying by chain and franchise pharmacies;
- increased generic competition; and
- a wholesaler upcharge, not recoverable by the pharmacist, which rewards those who purchase directly from the manufacturer.

In addressing these problems, the Committee believed that certain principles had to be protected: drugs must be available quickly to all who need them, without regard for geographic location; distribution should be revenue-neutral to pharmacists; the recommendations should not require additional public funds; the recommendations should not result in windfall “distribution profits” for manufacturers; and distribution costs should be paid by those who incur them.

The Committee considered alternatives and asked for responses from interested outside parties. After presenting a number of alternatives in the third quarterly report, the Committee held a day of open hearings to further illuminate the situation. With the broader picture now emerging, the Committee puts forward recommendations which addressed the principles defined earlier. These include: the establishment of minimum standards for wholesalers which address fast, province-wide

distribution; permitting wholesalers to enter into agency distribution agreements with manufacturers; reduction of the percentage added to BAP to reflect the actual amount the pharmacist must pay to the wholesaler and eliminating the upcharge added to BAP for direct sales; ensuring that no increase in BAP is allowed when a manufacturer moves from indirect to direct sales; and renegotiation of the fee structure by which pharmacists are reimbursed to reflect the reduced upcharge and the expanded professional role of the pharmacist.

The chapter examines the problems with Ontario Government Pharmaceutical and Medical Supply Services (OGPMSS) and recommends that: psychiatric hospitals be allowed to use the group purchasing plan of the Ontario Hospital Association; that MOH engage an outside group of consultants to examine the possibility of MOH divesting itself of purchasing, warehousing and distribution functions carried out through OGPMSS or supply and services branch, and to develop efficient alternatives to services being provided for long-term care facilities.

The section on drug distribution concludes by examining the hospital unit dose system and recommends that the unit dose/IV admixture program be the system of choice for drug delivery in hospitals above a certain size and that hospitals receive funding for conversion to the unit dose system.

### ***Chapter VII The Prescribing of Drugs***

The role of the physician in the drug prescription scenario is examined from both the theoretical and practical points of view. The seventh chapter considers the prescribing of drugs, the key role of the physician as prescriber, the education of physicians for this role and the ways in which prescribing can be improved.

Information models which illustrate the factors affecting physicians' decisions are reviewed and the recommendation is made that rational pharmacotherapy should be the goal for all concerned with the use of prescription drugs in Ontario.

The Committee also recommends investigation of the possibility of shared funding between the industry and the MOH for an Ontario centre for the study and improvement of drug prescribing. Discussions on informed consent to treatment and the physician's role as either patient advocate or gatekeeper for society lead to the recommendation that individual prescribers remain responsible for individual patients, while organized medicine should play a role in protecting society's resources.

Physician education as it relates to therapeutics—at the undergraduate, postgraduate and continuing medical education levels—receives attention. The Inquiry concludes that prescribing strategies are insufficiently addressed in basic medical pharmacology courses and training in prescribing depends on variable apprenticeship experiences. To address this deficiency, the Inquiry recommends initiatives at each of Ontario's medical schools to: change curricula to emphasize good prescribing practices; integrate basic and clinical sciences, particularly pharmacology and pharmacotherapy; recognize the differences in the type of morbidity found in teaching hospitals and community practice; place more emphasis on the critical appraisal of drug products and on treatment needs of the elderly.

At the postgraduate level, initiatives should include regular review of pharmacological aspects of therapy; improved integration of clinical pharmacology in all services including surgical

units; improved auditing procedures regarding the use of drug products; and a specific geriatric experience at the intern and residency level.

In order to ensure that health care providers have access to information that promotes rational prescribing on a continuing basis, the Committee recommends effective programs in continuing medical education; innovative post-marketing surveillance studies which involve large numbers of family practitioners, and development of pilot drug utilization review programs.

After examining attitudes of physicians to their education as a preparation for prescribing drugs, as well as the roles of government and the medical associations, the Committee recommends the development of prescribing guidelines by organized medicine.

The Committee also makes recommendations in connection with a regularly updated publication containing guidelines for prescribing based on objective information about preferred drug products; the restricted use of especially expensive medications for which less costly alternatives are available; continued development and use of restricted hospital formularies; extension of the restricted formulary approach to group clinics and other health care facilities; the use of generic names in writing and labelling of prescriptions; and the promotion of regular organized reviews of drug treatment.

Turning to the relationship between manufacturers and physicians, the Committee recommends pilot projects to test unbiased non-commercial detailing and the development of ethical guidelines for physician/ industry interaction. The chapter concludes with discussion and recommendations concerning: the

establishment of a department of clinical pharmacology in each Ontario medical school; mechanisms for increased liaison between physicians and pharmacists; creation of a drug information service to provide assessment of high cost drugs; and review of over-the-counter medications listed in the formulary to assign them either to the general or restricted use categories.

### ***Chapter VIII Dispensing/ Administration***

One of the main areas of the Inquiry's mandate deals with the dispensing of drugs and the role of the key player in that function—the pharmacist; this section on dispensing constituted the subject of the Inquiry's fourth interim report. The Committee believes that the recommendations in this area will, if adopted, lead to a far-reaching and desirable redefinition of the role of the pharmacist and that Ontario has an opportunity to exert national and international leadership in this regard.

In developing the recommendations, the Committee considered that the responsibilities of the pharmacist encompass two main functions: cognitive, patient-oriented activities, such as consulting with patients, prescribers and other health care professionals, and those which are product-oriented, such as acquiring, storing, labelling, packaging, dispensing and record keeping. Problems related to both of these functions are reflected in the report.

The economics of current community pharmacy practice may have a negative impact on the provision of patient-oriented services because the payment system is structured to reimburse pharmacists on the basis of drugs dispensed rather than professional

services rendered. Strategies are required to reward delivery of desirable patient-oriented services while the traditional responsibility for the dispensing functions of the pharmacist is maintained. The report also examines factors leading to change in the practice of pharmacy, such as changes in public and professional expectations, the ageing of our population, pressures to contain costs, demand for pharmacists exceeding supply, increasing professional specialization, changing technology and questions about maintaining professional competence.

Product-related recommendations deal with the expanding role of non-professional auxiliary personnel, information systems to deal with adverse drug interaction information, packaging standards and consumer-friendly labelling, specifically as this relates to patients with special information needs.

Patient-related recommendations cover public education, with particular emphasis on seniors; necessity for medication profiles; "smart cards; " pharmacists' access to patient diagnoses; reimbursement for patient consultation; an expanded clinical role for pharmacists; community drug therapy committees; and recommendations dealing with changes in the education of the professional. Recommended changes in education include a restructuring of current pharmacy training; a reduction in the size of the University of Toronto's pharmacy faculty; the creation of a new faculty of pharmacy; the creation of a doctoral program in pharmacy; joint instruction for students of the faculties of pharmacy and medicine; and increased emphasis on inter-professional communications in the training of medical, nursing and pharmacy students.



## *Chapter IX Utilization*

This chapter, on consumers and pharmaceutical care, synthesizes diverse data to present a demographic profile of the consumers of health services in Ontario.

An examination of coverage under the Ontario Drug Benefit plan, as well as private health care insurance, reveals that there are special problems of access to needed drugs related to certain categories of individuals, particularly low income individuals and families not covered by old age and social assistance benefits, and individuals with catastrophic drug costs. The Committee recommends that drug costs for these categories now be covered, but that there should be a co-payment for those with incomes above social assistance levels. A second recommendation, which follows an examination of demand elasticity when consumers have to pay part of their drug costs, is that recipients of ODB benefits who are not on social assistance should pay a portion of each prescription, up to a maximum of \$250 per year.

A drug utilization review (a form of quality assurance which can improve prescribing and, therefore, the health of the public) must include information on four interrelated items: drug (therapy); patient (diagnosis); physician (prescriber); and pharmacy (dispensing record). Conducted appropriately, the Committee believes, systematic utilization review will also prevent waste and save money.

The Committee also recommends an adverse drug reporting program supported by the province. Such a program has been in operation since 1981, and is currently conducted by the Ontario Medical Association as a public service. However, economic constraints are now threatening the continuation of

this program and the Inquiry believes that, because its preservation has merit, the province should take steps to ensure its survival.

The chapter also deals with the misuse and abuse of prescription medications. The Inquiry examines factors contributing to abuse, such as levels of use, consumer demand and social expectations, and the role of manufacturers and physicians. It also examines the illegal use of prescription drugs which, according to the RCMP, the OPP and the Metropolitan Toronto Police, is an increasing problem.

Vigorous public education programs involving schools, the media, our three levels of government, industry, labour and community groups are required in educating the public regarding the dangers of abusing and misusing drugs and it is recommended that the three levels of government should set up appropriate mechanisms to make drug abuse, including misuse of prescription drugs, as socially undesirable as smoking cigarettes has become.

On the assumption that prevention is better than treatment, the Inquiry recommends that prescriptions for hypnotics, sedatives and tranquilizers be for the shortest time possible and, where indicated, be clearly marked "no repeats." Research into the various approaches to reducing over-use of these substances should be undertaken.

## *Chapter X Alternative Therapies*

While the Committee was not asked to look at alternatives to prescription drugs, a number of submissions called attention to this issue, and there is a large body of professional and lay literature related to the danger of the type of thinking which suggests a "pill for every ill."

While the report does not attempt a systematic examination of alternatives to prescription drugs, it concludes that such a study, conducted in accordance with accepted scientific standards, is merited. As an example of areas that merit more careful examination by both experts and policymakers, a brief look at the role of nutrition in health and illness is included.

The chapter does not contain any specific recommendations, but suggests the following:

- a critical review, sponsored by the Ministry of Health, of the extensive but largely anecdotal literature on nutritional pharmacology;
- increased support for departments of nutritional science in Ontario faculties of medicine and joint studies with appropriate clinical departments;
- a consensus conference of leading clinicians, nutritional scientists and physicians experienced in the use of nutritional treatments to explore the state of the art;
- examination of the implications for nutritional treatment in the recommendations of the Health Professions Legislation Review (Schwartz Report.)

### ***Chapter XI Pharmacotherapy for the Elderly***

The impaired organ systems of the elderly do not handle drugs as efficiently as those of younger people and medication in this group carries a risk because dosing regimens must be modified to take into account the absorption, distribution, metabolism, elimination and drug response characteristics of the elderly body.

The Ontario Drug Benefit formulary should list medications appropriate for the elderly and the Committee recom-

mends that the DQTC review the availability of liquid formulations of such drugs as iron, acetaminophen and others where appropriate.

The present and soon-to-be older generations will, in all likelihood, continue to experience a significant amount of chronic disease that may be ameliorated by rational pharmacotherapy. A study commissioned by the Inquiry shows that 80 per cent of all adverse drug reactions (ADRs) are due to the extension of known pharmacologic properties and are potentially avoidable.

Major causes of ADRs, the study shows, are polypharmacy, self-medication, lack of compliance with instructions, improper storage, physicians' lack of training in geriatric prescribing, problems with supervision of elderly patients, dual prescribing systems in hospitals and in post-discharge care, and increased drug sensitivity in the elderly. To deal with this, the Committee has recommended that smart cards to be introduced to facilitate drug utilization, monitoring and review, be programmed to ensure that problems in pharmacotherapy are promptly identified and that the electronic communication system recommended for pharmacies should be programmed to take into account special problems in prescribing for the elderly.

There is also an important role for manufacturers in ensuring the safety of new drugs. Whenever it is feasible, data from drug trials submitted in support of applications for licensing and listing should include data from older individuals and, where it is relevant, manufacturers should provide data and recommendations for prescribing to older patients.

Faculties of medicine sponsoring drug trials should be asked to include older subjects.

As the elderly are especially prone to multiple illnesses, they are particularly liable to suffer adverse reactions due to drug interactions, particularly if multiple prescribers do not know about other drugs a patient is taking.

To deal with this, the Committee has recommended that: the elderly choose one personal primary care physician; specialists and hospital clinics inform the patient's attending physician of alterations in the patient's drug regimen; guidelines be established to ensure primary care physicians maintain and update seniors' medication lists; and physicians be encouraged to recommend that patients on complicated drug regimens bring all medications on each visit to a doctor or hospital.

To ensure that physicians and other health care providers are properly educated to provide care for the elderly, the Committee is requesting faculties of medicine to review curricula to ensure that appropriate instruction and experience are provided in prescribing for the elderly and that family medicine and specialty postgraduate training programs have specific rotations in geriatric medicine, including supervised pharmacotherapy experience. At the same time, the Ontario Medical Association, the Royal College of Physicians and Surgeons of Canada and the College of Family Practice are requested to review educational objectives and initiatives with regard to pharmacotherapy for the elderly.

The chapter concludes with a recommendation that all acute care hospitals and geriatric long-term facilities establish systems to monitor the pharmacotherapy of elderly patients.

## **Chapter XII—Conclusions and Recommendations**

The final chapter concludes that Ontarians generally do receive excellent treatment involving prescription drugs and deals briefly with the problems that were identified. Recommendations are defined by category: those intended to improve the quality of treatment involving prescription drugs and those designed to improve access to needed drug treatment.

An examination of the cost implications of the various recommendations dealing with the Ontario Drug Benefit program reveals that, using mid-range estimates, the implementation of all recommendations would add about \$95 million and save \$195.5 million, for a net saving of about \$100 million annually. This is equivalent to a 15 per cent reduction in the annual cost of the program.

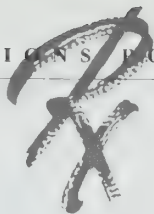
Looking at the economic impact of other recommendations, the section concludes that changes to the Drug Quality and Therapeutics Committee and the education of pharmacists would add about \$5.3 million per year.

It is impossible to estimate the cost implications associated with a number of other categories of recommendations.

The chapter concludes with a listing of all the recommendations contained in the report.



*[Note : Dans ce texte, lorsqu'il désigne des personnes, le masculin est utilisé au sens neutre.]*



## Rapport administratif

### Rapport du Comité d'enquête de l'Ontario sur les produits pharmaceutiques

*Le Comité d'enquête de l'Ontario sur les produits pharmaceutiques a été institué pour examiner le rôle et l'influence du gouvernement de l'Ontario en matière de produits de prescription. Bien que sa création soit en partie attribuable aux inquiétudes quant à l'escalade rapide du coût des programmes gouvernementaux pour les médicaments—environ 20 p. 100 par an et 508 p. 100 au cours de la dernière décennie—le comité d'enquête n'a pas considéré le freinage des coûts comme sa tâche unique, ou même primordiale.*

*Le rapport renferme 147 recommandations. La plupart sont adressées au gouvernement de l'Ontario, qui a commandé l'enquête, mais certaines devront être examinées par les associations professionnelles, les organismes légaux qui réglementent les professions de la santé en Ontario, les cinq centres universitaires des sciences de la santé, les fabricants et distributeurs de produits pharmaceutiques, et la population.*

*Nous sommes convaincus que la mise en oeuvre de ces recommandations contribuera à la prestation d'un traitement accessible et de haute qualité aux Ontariens qui ont besoin de produits de prescription et aidera à éliminer les dépenses publiques inutiles.*

*Le comité a atteint plusieurs conclusions importantes :*

#### A

Les Ontariens reçoivent généralement un excellent traitement en ce qui a trait aux produits de prescription. La plupart du temps, les produits pharmaceutiques sont sûrs et efficaces, et leur prescription, délivrance et usage sont appropriés. Les produits de prescription sont généralement disponibles promptement. Ils sont d'un prix abordable pour la plupart des Ontariens; environ 1,5 million de personnes (16 p. 100 de la population), y compris toutes les personnes âgées et les bénéficiaires de l'aide sociale, sont admissibles aux programmes pour les médicaments financés par le gouvernement. En outre, environ 6,7 millions de personnes (70 p. 100 de la population) ont accès à des régimes privés couvrant la majorité ou la totalité de leurs dépenses en médicaments; plusieurs autres citoyens ontariens paient leurs médicaments de leur poche.

Étant donné que les produits de prescription sont une composante importante des soins de santé actuels, le comité a trouvé ces conclusions rassurantes.

## B

Toutefois, même les bons programmes peuvent être améliorés. Le comité a identifié un certain nombre de problèmes auxquels il faut faire attention et sur lesquels portent les recommandations. En voici quelques-uns :

- Certains produits pharmaceutiques inscrits au Formulaire du Programme de médicaments gratuits de l'Ontario (dont les coûts sont remboursés par les fonds publics) ne sont pas d'une efficacité optimale et/ou présentent un rapport bienfait/risque désavantageux.
- Certains médecins ne prescrivent pas les médicaments d'une manière utile ou efficace; les erreurs dans la prescription sont particulièrement inquiétantes dans le cas des personnes âgées. On se préoccupe notamment du fait que certains médecins prescrivent des médicaments puissants, alors que d'autres modalités thérapeutiques seraient plus sûres ou plus efficaces. Certains médecins prescrivent de façon impropre des produits nouveaux et coûteux, avant d'essayer des médicaments plus économiques et bien reconnus.
- Les médecins ne sont pas aussi bien préparés qu'ils le pourraient, du point de vue académique, à prescrire les milliers de produits pharmaceutiques disponibles, particulièrement en ce qui a trait aux personnes âgées. La formation continue des médecins concernant l'usage des nouveaux produits pharmaceutiques doit être améliorée.
- Les pharmaciens ne réalisent pas pleinement leur potentiel professionnel, en tant que participants à la prestation de soins de santé.
- Certains Ontariens qui ont besoin de produits de prescription n'y ont pas facilement accès; ils ne sont pas admissibles aux programmes gouvernementaux parce qu'ils ont moins de 65 ans et ne reçoivent pas d'aide sociale, ni ne peuvent s'assurer adéquatement dans le domaine privé. Les deux groupes les plus menacés sont les personnes qui n'ont pas d'assurance au travail et qui touchent de faibles salaires (les «travailleurs pauvres») et les personnes dont les frais en médicaments sortent de l'ordinaire, en raison de maladies chroniques graves ou d'invalidité. On estime que de 600 000 à 700 000 personnes appartiennent à l'un de ces groupes et n'ont pas adéquatement accès aux médicaments dont ils ont besoin.

## C

Au Canada, les gouvernements doivent continuer à assumer la principale responsabilité dans le domaine des produits de prescription; en particulier ils doivent s'assurer que les médicaments sont sûrs, efficaces et abordables. La coordination entre les ministères fédéral et provinciaux n'a pas atteint des conditions optimales. Il n'existe pas de ligne de conduite nationale quant à l'interchangeabilité des médicaments; de plus, le processus d'approbation et d'autorisation des produits est plus complexe et lent que nécessaire.

Bien que les lignes de conduite du gouvernement provincial encouragent l'usage de produits pharmaceutiques «d'appellation commune», les frais en produits de prescription n'ont pas été bien maîtrisés.

Des recommandations ont été formulées pour trouver une solution à ces problèmes, ainsi qu'aux autres questions identifiées par le comité d'enquête.

*Les lecteurs trouveront ci-après un résumé du rapport présenté chapitre par chapitre.*



## Chapitre I Introduction

Le comité d'enquête a reconnu qu'il était impossible d'examiner en profondeur le vaste mandat qu'on lui a confié dans le délai prescrit de 19 mois, lequel fut par la suite porté à 22 mois. Il a décidé de concentrer ses efforts sur les trois principaux objectifs de son mandat : améliorer la qualité de la pharmacothérapie en Ontario; assurer à tous les Ontariens un accès approprié aux médicaments nécessaires; et freiner la hausse des coûts des produits de prescription, qui ont subi une augmentation vertigineuse.

Au cours des travaux du comité d'enquête, nombre de groupes et de particuliers ont apporté des conseils, de l'aide et de l'information—parfois sans avoir été sollicités, mais le plus souvent dans le cadre d'audiences publiques ou en réponse directe à des demandes précises. Le comité d'enquête a également examiné les programmes gouvernementaux sur les médicaments, des études et des rapports antérieurs, ainsi que les lois pertinentes; il a aussi commandé des projets de recherche pour fournir de l'information complémentaire.

Quatre rapports intérimaires ont été remis à la ministre de la Santé; ils sont présentés intégralement en annexe. Les constatations et les recommandations qu'ils renferment sont présentées dans le contexte approprié dans le cadre du rapport.

## Chapitre II Les objectifs du comité d'enquête

Le comité d'enquête tient pour acquis que les Ontariens devraient profiter d'un système leur assurant des thérapies médicamenteuses optimales qui soient appropriées, accessibles et abordables, et qui conservent nos ressources peu abondantes. Dans le domaine des soins de santé, le rôle joué par les produits de prescription varie en importance : rôle important dans le traitement des maladies et

dans le soulagement des symptômes, et rôle secondaire dans la promotion de la santé, la prévention des maladies et la réhabilitation, ainsi que dans la lutte contre le stress. Les produits d'ordonnance n'ont aucun rôle à jouer dans les activités de loisir.

Le comité d'enquête a examiné le rôle approprié des gouvernements et conclu que, bien que les groupements professionnels et les consommateurs aient un rôle important à jouer concernant la prescription, la dispensation et l'utilisation des produits d'ordonnance, la responsabilité principale pour que les médicaments soient de bonne qualité, d'un accès approprié et d'un prix abordable, incombe au gouvernement, le ministère de la Santé de l'Ontario jouant un rôle de chef de file dans chacun de ces cas.

## Chapitre III Programmes concernant les produits de prescription en Ontario

Le chapitre trois passe en revue l'histoire des programmes concernant les produits de prescription en Ontario.

Le financement public des produits de prescription en Ontario découle de la Loi fédérale de 1958 sur l'assurance-hospitalisation et les services diagnostiques (l'Ontario y a adhéré en 1959). En vertu de ce programme, les produits d'ordonnance étaient au nombre des services médicaux assurés dispensés dans les hôpitaux. Au cours des années qui suivirent, certains programmes des gouvernements municipaux, provinciaux et fédéral offrirent divers soins de santé aux personnes ayant besoin de l'aide sociale; de même, les régimes privés d'assurance-maladie commencèrent également à contribuer aux frais des médicaments.

La Commission royale Hall de 1964 a posé les bases de la Loi canadienne sur la santé (1968), sur laquelle repose notre système de soins de santé.

La Commission Hall a recommandé que les produits de prescription pour les malades externes, ainsi que les produits administrés dans les hôpitaux, soient assurés au titre du régime public, et proposé le versement d'une contribution de 1 \$ pour la plupart des ordonnances. Cependant, contrairement à cette recommandation, le programme national d'assurance-maladie établi en vertu de la Loi canadienne sur la santé ne couvrait pas les produits de prescription des malades externes.

Vers la fin des années 1960, le gouvernement provincial prit des mesures pour faciliter la prescription des produits pharmaceutiques d'appellation commune. C'est aussi pendant cette période que fut créé le Comité d'appréciation des médicaments et des thérapeutiques, un groupe consultatif au ministre de la Santé indépendant chargé d'assurer la qualité des produits pharmaceutiques en Ontario. L'Index comparatif des médicaments (ICM), qui est à l'origine du Formulaire du Programme de médicaments gratuits de l'Ontario, remonte également à cette période.

En 1974, le gouvernement provincial a introduit le Régime de médicaments gratuits de l'Ontario, qui visait initialement à fournir des médicaments gratuits aux personnes âgées admissibles aux prestations de supplément garanti du revenu et aux bénéficiaires des autres programmes d'aide sociale du gouvernement. Un an plus tard, le programme était offert à tous les citoyens ontariens de plus de 65 ans. Les prestations admissibles étaient inscrites dans le Formulaire qui, par la publication du montant remboursable par le gouvernement pour chaque produit pharmaceutique, fixait des limites de prix pour les médicaments de sources multiples. Le Comité d'appréciation des médicaments et des thérapeutiques faisait des recommandations quant aux médicaments à inscrire dans le Formulaire, s'assurait de la qualité des produits et déterminait leur interchangeabilité.

C'est à la fin de 1986 que sont entrées en vigueur les lois 54 et 55, respectivement la Loi sur les médicaments gratuits de l'Ontario et la Loi sur la réglementation des prix des produits de prescription. La loi 54 donnait au gouvernement le pouvoir de gérer effectivement le Régime de médicaments gratuits de l'Ontario, tandis que la loi 55 visait à fournir aux consommateurs l'information dont ils ont besoin pour être bien renseignés et réaliser des économies dans l'achat de médicaments.

Entre 1978 et 1988, le Régime de médicaments gratuits de l'Ontario a connu une augmentation annuelle moyenne de 20,4 p. 100, ce qui le classe parmi les programmes de soins de santé dont la croissance fut la plus rapide au cours de cette période. Au cours de l'exercice 1988-1989, le montant total versé pour ce programme s'est élevé à 637,9 millions de dollars.

#### **Chapitre IV Le Formulaire et le Comité d'appréciation des médicaments et des thérapeutiques**

Le comité d'enquête estime qu'un certain nombre de lacunes sont imputées au Formulaire, dans sa forme actuelle : il ne contient pas d'information quant aux doses courantes; il ne recommande aucune stratégie de traitement; il n'a pas la réputation d'être facile d'usage. Et, plus important encore, il n'est pas utilisé par les prescripteurs. Le comité a considéré deux options : éliminer ou modifier le Formulaire. En fin de compte, il a retenu cette dernière solution.

Pour effectuer les changements voulus, le comité a formulé des recommandations en vue de : la création d'un nouveau formulaire; une révision de tous les produits inscrits actuellement, en ce qui a trait à leur efficacité, leur sûreté, leur équivalence et leur coût; l'établissement de catégories pour les médicaments à usage général et à usage restreint; l'exemption de la demande du fabricant pour l'inscription des médicaments;

l'évaluation régulière des produits; la surveillance en vue d'accroître la responsabilité des prescripteurs; la possibilité d'accorder des remboursements sur les produits non-inscrits au Formulaire; des inscriptions pour les produits sous forme posologique non usuelle; des mécanismes en vue de promouvoir la prescription de médicaments d'appellation commune; et un système permanent pour l'évaluation des produits.

Le Comité d'appréciation des médicaments et des thérapeutiques décide des médicaments à inscrire au Formulaire, de la catégorie où ils seront placés et de l'interchangeabilité des produits. Il est composé de médecins, de pharmaciens et de scientifiques, qui s'appuient sur leur expertise reconnue pour conseiller la ministre; ils sont aidés par des experts-conseils indépendants qui leur fournissent des études et les avisent. Le comité d'enquête a reçu certains mémoires recommandant la dissolution du Comité d'appréciation des médicaments et des thérapeutiques, mais bien qu'il soit possible d'envisager certaines solutions de rechange, il n'existe aucune raison concluante de procéder à un tel changement. Le comité recommande toutefois : d'élargir son mandat en vue de permettre une évaluation plus efficace des facteurs de coût et des effets des modifications apportées au Formulaire; et d'intensifier la communication entre les professionnels de la santé et le Comité d'appréciation des médicaments et des thérapeutiques.

En ce qui a trait aux produits sous «autorisation spéciale» (AS)—médicaments non-inscrits au Formulaire ordinaire mais jugés nécessaires à la santé dans des cas particuliers—le comité a recommandé dans son rapport intérimaire de décembre 1988 que le programme d'AS soit discontinué et que tous les médicaments autorisés dans le cadre du Programme de médicaments gratuits de l'Ontario soient approuvés par le Comité d'appréciation des médicaments et

des thérapeutiques. Au nombre des autres recommandations dans ce domaine, le comité d'enquête préconise également que le Formulaire renferme les catégories usage limité et usage ordinaire, et que le Comité d'appréciation des médicaments et des thérapeutiques crée un mécanisme lui permettant d'étudier rapidement les produits qui représentent des progrès thérapeutiques majeurs.

À propos de l'interchangeabilité des médicaments, le comité recommande de continuer à respecter la ligne de conduite actuelle encourageant la substitution par des produits d'appellation commune; les pharmaciens devraient continuer d'être remboursés seulement au prix du produit pharmaceutique équivalent le moins coûteux et devraient renouveler les ordonnances avec les produits dispensés initialement, lorsque les prix sont équivalents; ils devraient être remboursés pour une ordonnance «sans substitution» mettant en cause un produit plus coûteux, seulement lorsqu'il y a une raison approuvée de la faire; le patient devrait avoir la possibilité de payer la différence de prix dans le cas des ordonnances «sans substitution»; des dispositions spéciales devraient être prises si le patient ne peut tolérer le produit moins coûteux; le pharmacien devrait aviser le patient et le prescripteur lorsqu'un produit a été remplacé; et les fabricants devraient diffuser l'information nécessaire lorsqu'un nouveau produit d'appellation commune entre en usage général.

**4.1 Par conséquent, le comité recommande que le Formulaire du Programme de médicaments gratuits de l'Ontario soit conservé, mais qu'il soit modifié en profondeur.**

**4.2 Par conséquent, le comité recommande qu'après la publication de l'édition de janvier 1991, le Formulaire soit gelé pour permettre la création d'un formulaire nouveau et allégé. Les avantages cités dans**



l'édition de janvier 1991 seraient offerts seulement jusqu'à la publication du formulaire allégé; à ce moment, tous les avantages en vigueur prendraient fin et seraient remplacés par les dispositions du nouveau formulaire.

4.3 Par conséquent, le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques entreprenne immédiatement une révision de tous les produits inscrits actuellement dans le Formulaire, en ce qui a trait à leur efficacité, leur sûreté, leur équivalence et leur coût.

4.4 Par conséquent, le comité recommande la mise au point de mécanismes permettant l'inscription de produits pharmaceutiques sous la recommandation du Comité d'appréciation des médicaments et des thérapeutiques, même lorsqu'aucune demande n'a été présentée par le fabricant.

4.5 Le comité recommande en outre que des dispositions soient prises pour donner au Formulaire un caractère dynamique; les produits provenant de sources multiples et les produits provenant d'une seule source seraient réexaminés régulièrement, pour être conservés, éliminés ou changés de catégorie.

4.6 Par conséquent, le comité recommande que le ministère de la Santé, en collaboration avec le College of Physicians and Surgeons of Ontario, le Collège royal des chirurgiens dentistes d'Ontario, l'Association des médecins de l'Ontario, l'Ordre des pharmaciens de l'Ontario et l'Ontario Pharmacists' Association, lance d'ici le 1<sup>er</sup> janvier 1992 un programme destiné à surveiller l'utilisation médicamenteuse et accroître la responsabilité des prescripteurs à l'égard de leur pharmacothérapie.

4.7 Par conséquent, le comité recommande que le développement et l'utilisation de produits de sources multiples sous des formes posologiques non usuelles soient encouragés lorsque cela est possible, en assemblant et en promulguant des critères permettant l'identification et l'inscription de produits interchangeables sous des formes posologiques ou d'administration non usuelles.

4.8 Par conséquent, le comité recommande que le ministère de la Santé, le College of Physicians and Surgeons of Ontario, le Collège royal des chirurgiens dentistes d'Ontario, l'Association des médecins de l'Ontario et le Council of Faculties of Medicine collaborent à la mise au point de mécanismes en vue de promouvoir la prescription de médicaments d'appellation commune, lorsque cela est pertinent.

4.9 Par conséquent, le comité recommande qu'après l'édition de janvier 1991, le ministère discontinue le système actuel de publication du Formulaire, en vertu duquel des échéances semestrielles sont établies, et mette au point pour le remplacer un système permanent de révision des produits.

4.10 Par conséquent, le comité recommande que l'on retienne les services d'un comité consultatif spécialiste en matière de produits, tel que représenté par le Comité d'appréciation des médicaments et des thérapeutiques actuel, avec des attributions semblables à celles déjà établies, compte tenu des modifications proposées à la recommandation 4.11.

4.11 Par conséquent, le comité recommande que le mandat du Comité d'appréciation des médicaments et des thérapeutiques soit révisé d'ici le 1<sup>er</sup> janvier 1991 et que les points suivants soient examinés

a) Un mandat élargi permettant une évaluation plus efficace des facteurs de coût des produits pharmaceutiques; et

b) Un mandat élargi, accompagné des ressources appropriées, permettant de surveiller les effets des modifications apportées au Formulaire.

4.12 Par conséquent, le comité recommande que le Ministère et le Comité d'appréciation des médicaments et des thérapeutiques jouent un rôle plus actif en communiquant régulièrement avec les professionnels de la santé pour souligner les avantages du Formulaire et le processus de révision.

4.13 Que le programme d'autorisation spéciale soit discontinué sous sa forme actuelle.

4.14 Que tous les produits pharmaceutiques devant être autorisés aux fins de paiement en vertu du Programme de médicaments gratuits de l'Ontario soient approuvés par le Comité d'appréciation des médicaments et des thérapeutiques. (Voir la recommandation 4.20 sur la période de transition.)

4.15 Que tous les produits pharmaceutiques approuvés aux fins de paiement par le ministère de la Santé soient inscrits dans le Formulaire et que soient précisées les conditions, le cas échéant, auxquelles ils peuvent être couverts en vertu du Programme de médicaments gratuits de l'Ontario.

4.16 Que le Comité d'appréciation des médicaments et des thérapeutiques révise complètement tous les produits pharmaceutiques pour lesquels des autorisations spéciales ont été délivrées. Nous recommandons en outre que ceci soit effectué par ordre de fréquence d'usage (en commençant par le produit le plus couramment utilisé), selon les critères

d'inscription au Formulaire. Tous les médicaments approuvés par le Comité d'appréciation des médicaments et des thérapeutiques après cette révision devraient être inscrits dans le Formulaire. Les médicaments qui ne reçoivent pas l'approbation du comité ne devraient pas être inscrits dans le Formulaire, ni être admissibles aux fins de paiement par le ministère de la Santé.

4.17 Que le Formulaire renferme deux catégories de médicaments : *usage ordinaire* et *usage limité*. Le coût des médicaments d'*usage ordinaire* devrait être remboursé chaque fois qu'ils sont prescrits et dispensés aux personnes admissibles aux programmes de médicaments gratuits de l'Ontario.

L'appellation *usage limité* pourra être accordée aux autres produits pharmaceutiques qui pourront seulement être remboursés à des conditions déterminées par le Comité d'appréciation des médicaments et des thérapeutiques et énoncées dans le Formulaire du Programme de médicaments gratuits de l'Ontario. Par exemple, l'appellation *usage limité* peut être accordée lorsqu'au moins une des conditions suivantes est remplie

- a) lorsque les conditions thérapeutiques limitées, déterminées par le Comité d'appréciation des médicaments et des thérapeutiques et énoncées dans le Formulaire du Programme de médicaments gratuits de l'Ontario, ont été remplies;
- b) lorsque les médicaments d'*usage ordinaire* ont été essayés et se sont révélés inefficaces ou ont causé des effets indésirables chez un patient particulier; et
- c) lorsque des médicaments d'*usage ordinaire* de rechange sont contre-indiqués, en raison d'une thérapie coexistante ou de particularités chez un patient.

Le prescripteur aurait la responsabilité professionnelle de s'assurer que la (les) condition(s) a (ont) été remplie(s).

4.18 Que les conditions et restrictions, le cas échéant, sous lesquelles les médicaments seront autorisés aux fins de remboursement soient clairement indiquées. Ceci peut être fait par des notes en bas de page ou d'autres indications dans le Formulaire.

4.19 Que tous les produits pharmaceutiques pour lesquels des autorisations spéciales ont été délivrées dans le passé, après avoir été revus par le Comité d'appréciation des médicaments et des thérapeutiques, se retrouvent dans seulement une des catégories suivantes

- a) Inscription dans le Formulaire avec l'appellation *usage ordinaire*;
- b) Inscription dans le Formulaire avec l'appellation *usage limité*; et
- c) inadmissibilité à un remboursement par le gouvernement de l'Ontario.

4.20 Que pendant la période de transition, jusqu'à ce que le Comité d'appréciation des médicaments et des thérapeutiques ait pu réviser les médicaments pour lesquels des autorisations spéciales ont été délivrées, tous les médicaments sous autorisation spéciale en instance de révision puissent conserver leur autorisation spéciale. On devrait toutefois imposer un strict moratoire sur l'attribution de l'appellation autorisation spéciale à de nouveaux produits.

4.21 Que le Comité d'appréciation des médicaments et des thérapeutiques crée un mécanisme lui permettant d'étudier rapidement les nouveaux produits présentant des progrès thérapeutiques majeurs.

4.22 Par conséquent, le comité recommande que, bien que la ligne de conduite actuelle de l'Ontario sur l'interchangeabilité des médicaments, qui encourage la

substitution par des produits d'appellation commune et la compétitivité en matière de prix, soit maintenue.

- a) L'Ordre des pharmaciens d'Ontario demande aux pharmaciens de renouveler les ordonnances avec les produits dispensés initialement lorsque leur prix est équivalent à celui de produits concurrentiels. (Il est entendu que, lorsqu'il existe une différence substantielle de prix, les pharmaciens dispenseront le produit pharmaceutique à un prix correspondant au niveau auquel ils seront remboursés.)
- b) Les ordonnances «sans substitution» ne soient plus admises au titre du Programme de médicaments gratuits de l'Ontario; lorsque le patient demande que le produit spécifiquement prescrit soit dispensé, il devrait combler l'écart de prix par rapport au produit le moins coûteux pour lequel le pharmacien sera remboursé.
- c) Le ministère de la Santé, sur l'avis du Comité d'appréciation des médicaments et des thérapeutiques, établisse un mécanisme par lequel un médecin peut demander qu'un produit particulier soit admis à titre de bénéfice (le coût du produit serait entièrement remboursable au pharmacien) dans les très rares cas où un patient ne peut tolérer le produit le moins cher ou en bénéficier.
- d) Les lignes de conduite et, au besoin, la législation soient modifiées afin d'exiger que les pharmaciens informent les patients et les prescripteurs de la substitution d'un produit.
- e) Lorsqu'une nouvelle préparation d'appellation commune entre en usage général, le ministère de la Santé exige que le fabricant du produit d'appellation commune diffuse l'information nécessaire aux prescripteurs, tout comme le font maintenant les fabricants de produits novateurs.



**4.23 Par conséquent, le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques soit habilité à examiner les demandes et à faire des recommandations au ministre de la Santé concernant l'interchangeabilité des produits pharmaceutiques, indépendamment de la situation des produits au titre du Programme de médicaments gratuits de l'Ontario. Si l'on juge nécessaire de changer la législation ou les règlements pour que cela soit possible, le changement approprié devrait être institué.**

## **Chapitre V L'acquisition des médicaments**

L'industrie pharmaceutique se divise en deux grands groupes : les fabricants de produits novateurs et les fabricants de produits d'appellation commune. Au Canada, le segment des produits novateurs, ou marques commerciales, relève essentiellement des multinationales, par l'entremise principalement de leurs filiales de fabrication et de distribution. La croissance du segment des produits d'appellation commune, qui est constitué principalement de fabricants canadiens, est attribuable à la loi rendant obligatoire la détention de permis. Dans l'ensemble, cette industrie très rentable croît plus rapidement au Canada qu'à l'échelle mondiale.

Dans le cadre du Formulaire, la province établit le meilleur prix disponible (MPD), c'est-à-dire le prix le plus bas auquel le produit est disponible au Canada, aux fins de vente en Ontario. Pour être légalement commercialisé au Canada, un médicament doit être approuvé aux fins de vente par la Direction générale de la protection de la santé du gouvernement fédéral; ce processus d'approbation est parfois très lent. Par l'entremise du Comité d'appréciation des médicaments et des thérapeutiques, le gouvernement ontarien détermine si deux marques ou plus sont bioéquivalentes et

assume la responsabilité légale afin de permettre aux pharmaciens de dispenser la marque équivalente la moins coûteuse. Pour simplifier ce processus, le comité d'enquête recommande que l'Ontario prenne l'initiative dans la promotion d'une politique d'interchangeabilité à l'échelle du pays.

Le comité recommande également : l'établissement d'un plafond quant au prix d'introduction des nouveaux produits d'appellation commune; le maintien du concept du MPD; une formule pour rétrograder les prix des médicaments et empêcher les augmentations de dépasser l'IPC; une limite des futures augmentations de prix; un mécanisme de vérification permettant d'ajuster rétroactivement les sommes remboursées à certains pharmaciens; et l'exigence que les pharmaciens rapportent toutes les ordonnances non couvertes dans le cadre du Programme de médicaments gratuits de l'Ontario.

Ce chapitre porte également sur les programmes d'achat des hôpitaux. Il y est proposé d'approuver et d'appuyer le concept d'un formulaire réduit pour les petits hôpitaux, les maisons de soins infirmiers et les foyers pour personnes âgées, ainsi que pour les centres de médecine communautaire.

**5.1 Par conséquent, le comité recommande que le gouvernement de l'Ontario prenne l'initiative de promouvoir des ententes fédérale-provinciales et interprovinciales en vue d'une ligne de conduite sur l'interchangeabilité à l'échelle du pays. Santé et Bien-être social Canada devrait se voir confier un mandat plus vaste : en plus de confirmer la sûreté et l'efficacité des produits pharmaceutiques, le processus d'approbation devrait également déterminer si le produit est bioéquivalent à d'autres produits approuvés et s'il est interchangeable avec eux.**

5.2 Par conséquent, le comité recommande que l'équivalent sous appellation commune d'un produit de marque commerciale ne soit pas inscrit dans le formulaire pour la première fois à un prix supérieur à 60 p. 100 du prix de référence du produit de marque commerciale équivalent. Ce prix de référence sera le prix inscrit du produit de marque commerciale rencontré dans le formulaire antérieur à celui où le produit d'appellation commune est censé être inclus pour la première fois.

5.3 Par conséquent, le comité recommande que toutes les ordonnances pour des produits de sources multiples à l'intention de prestataires admissibles, indépendamment de leur désignation de produit «sans substitution» par le prescripteur, soient ordinairement remboursés uniquement au «meilleur prix disponible» le plus bas pour le produit. Si le pharmacien, à la demande du patient, dispense un produit dont le prix inscrit dépasse le MPD, le patient devra payer la différence au pharmacien. Le pharmacien peut être remboursé pour une ordonnance «sans substitution» mettant en cause un produit plus coûteux, seulement si le prescripteur a une raison approuvée d'avoir prescrit le produit. (Voir la recommandation 4.21)

5.4 Par conséquent, le comité recommande que le concept du meilleur prix disponible soit conservé, de préférence à d'autres formes de définition du prix de remboursement aux pharmaciens.

5.5 Par conséquent, le comité recommande que le prix de remboursement de tous les médicaments dans le formulaire de janvier 1991 soit ramené aux prix inscrits dans le formulaire de décembre 1986, plus les augmentations de l'indice des prix à la consommation de décembre 1986 à janvier 1991. Si le produit n'était pas inscrit dans le formulaire de décembre 1986, son prix de janvier 1991 devrait être ramené au prix

auquel il a été inscrit pour la première fois après décembre 1986, puis augmenté d'un montant ne pouvant pas dépasser l'augmentation de l'IPC entre cette date et janvier 1991. Si le prix ajusté en fonction de l'IPC est supérieur au prix actuel, le prix actuel devrait être maintenu.

5.6 Par conséquent, le comité recommande que, pour la période commençant avec le Formulaire suivant le formulaire de janvier 1991 et se terminant en janvier 1994, l'augmentation des prix des médicaments inscrits aux fins de remboursement ne dépasse pas 50 p. 100 de l'indice des prix à la consommation.

5.7 Par conséquent, le comité recommande que la législation actuelle soit amendée, avec des sanctions appropriées, pour renforcer le concept du meilleur prix disponible, de sorte qu'on exige des fabricants qu'ils signent une entente irrévocable les obligeant à offrir le format du produit à partir duquel le MPD a été établi, au prix inscrit, à toutes les pharmacies et à tous les grossistes, pendant la durée du Formulaire pertinent.

5.8 Le comité recommande en outre que le ministère de la Santé poursuive énergiquement les allégations de transactions ou de primes offertes par le fabricant, afin de réduire immédiatement le MPD en conséquence, si les allégations sont vraies.

5.9 Le comité recommande également que la législation soit amendée afin d'empêcher les pharmaciens de demander un remboursement (pour la portion du prix de l'ordonnance représentant le coût) en vertu du Programme de médicaments gratuits de l'Ontario, à un niveau supérieur au prix réellement payé pour le produit.

5.10 Le comité recommande en outre que la législation soit amendée de manière à exiger que les pharmaciens, lorsqu'ils

dispensent des ordonnances pour des produits interchangeables dans les cas de non-admissibilité au Programme de médicaments gratuits de l'Ontario, réclament pour la portion du prix de l'ordonnance représentant le coût du montant qu'ils ont payé réellement pour le produit, si celui-ci était inférieur au meilleur prix disponible.

## Chapitre VI La distribution des médicaments

La distribution des médicaments en Ontario est l'objet de certains problèmes importants qui ont trait à la modification des rapports entre les pharmacies de détail et les grossistes. Ce changement est attribuable à

- l'achat direct de groupe par les grandes chaînes de pharmacies et les pharmacies franchisées;
- la concurrence croissante des produits d'appellation commune; et
- un supplément du grossiste, qui ne peut être recouvré par le pharmacien et qui favorise ceux qui achètent directement du fabricant.

Dans son examen de ces problèmes, le comité a jugé que certains principes devaient être protégés : les médicaments doivent être rapidement disponibles pour tous ceux qui en ont besoin, quel que soit leur emplacement géographique; la distribution de devrait pas être productrice de revenus pour les pharmaciens; les recommandations ne devraient pas nécessiter de fonds publics additionnels; les recommandations ne devraient pas se traduire par des «bénéfices sur la distribution» inattendus, pour les fabricants; et les frais de distribution devraient être payés par ceux qui les engagent.

Le comité a examiné diverses possibilités et sollicité les commentaires de parties intéressées. Après avoir présenté un certain

nombre de propositions dans son troisième rapport trimestriel, le comité a tenu une journée d'audiences publiques pour mieux mettre en lumière la situation. Avec une meilleure vue d'ensemble, le comité a pu mettre de l'avant des recommandations en fonction des principes exposés plus haut.

Elles comprennent : l'établissement de normes minimums pour les grossistes afin de répondre au besoin d'une distribution rapide, à l'échelle de la province; permettre aux grossistes de conclure des ententes de distributeur-agent avec les fabricants; réduire le pourcentage ajouté au MPD afin de tenir compte du montant réel que doit payer le pharmacien au grossiste et éliminer le supplément ajouté au MPD pour les ventes directes; empêcher toute augmentation du MPD lorsqu'un fabricant de médicaments passe des ventes indirectes aux ventes directes; et renégocier la structure des honoraires selon laquelle les pharmaciens sont remboursés, pour refléter la diminution du supplément et l'élargissement du rôle professionnel du pharmacien.

On a également examiné dans ce chapitre les problèmes touchant l'Approvisionnement médico-pharmaceutique du gouvernement de l'Ontario (AMPGO) et recommandé : que les hôpitaux psychiatriques soient autorisés à utiliser le plan d'achat de groupe de l'Ontario Hospital Association; que le ministère de la Santé se départisse des fonctions d'acquisition, d'entreposage et de distribution, qu'il remplit par l'entremise de l'AMPGO ou sa Direction de l'approvisionnement et des services, et qu'il confie ces fonctions au secteur privé; et que le ministère de la Santé vérifie les services de l'AMPGO afin de mettre au point des solutions de rechange efficaces aux services offerts actuellement aux établissements de soins de longue durée.

La partie traitant de la distribution des médicaments se termine par un examen du système de dose unitaire en vigueur dans les



hôpitaux et la recommandation selon laquelle le programme pour la dose unitaire/mixtion intraveineuse soit adopté comme système de prédilection pour la délivrance de médicaments dans les hôpitaux d'une certaine grosseur et selon laquelle les hôpitaux reçoivent des subventions pour se convertir au système de dose unitaire.

**6.1** Par conséquent, le comité recommande l'établissement de normes minimums pour les services fournis par les grossistes, afin que leurs frais soient admissibles à des remboursements, comme le précise la recommandation 6.2 ci-dessous. Ces normes devraient comprendre la disponibilité ainsi que la distribution rapide et à l'échelle de la province de la plupart des produits de prescription.

**6.2** Par conséquent, le comité recommande que, tout de suite après avoir considéré ces recommandations, le ministère de la Santé permette aux grossistes de conclure des ententes de distributeur-agent avec les fabricants.

**6.3** Le comité recommande en outre que, pour coïncider avec la date d'entrée en vigueur des honoraires des pharmaciens, qui font actuellement l'objet de nouvelles négociations, le ministère de la Santé prenne des mesures appropriées pour ramener le pourcentage ajouté au meilleur prix disponible à un niveau destiné à dédommager le pharmacien du montant réel qu'il doit payer au grossiste, et pour éliminer complètement le supplément ajouté au MPD pour les ventes directes.

**6.4** Par conséquent, le comité recommande que le ministère de la Santé prenne les mesures appropriées pour empêcher toute augmentation du meilleur prix disponible lorsqu'un fabricant de médicaments passe des ventes indirectes aux ventes directes.

**6.5** Par conséquent, le comité recommande que dans le cadre de la négociation actuelle sur les honoraires de dispensation, le ministère de la Santé renégocie la structure des honoraires selon laquelle les pharmaciens sont remboursés, pour refléter la diminution du supplément et l'élargissement du rôle professionnel du pharmacien.

**6.6** Par conséquent, le comité recommande que, d'ici la fin de 1992, les hôpitaux psychiatriques soient autorisés à utiliser le plan d'achat de groupe de l'Ontario Hospital Association.

**6.7** Par conséquent, le comité recommande qu'on retienne les services d'un groupe d'experts-conseils indépendants pour effectuer une vaste vérification de l'organisation et de l'exploitation des services fournis par la Pharmacie du gouvernement, expressément dans le but de :

- a) étudier la possibilité que le ministère de la Santé se départisse des fonctions d'acquisition, d'entreposage et de distribution des produits pharmaceutiques, qui sont remplies actuellement par la Pharmacie du gouvernement ou par la Direction de l'approvisionnement et des services, de sorte que ces fonctions soient exécutées par des services du secteur privé, qui existent actuellement ou qui pourront être mis sur pied; ou
- b) étudier la possibilité d'améliorer l'efficacité de fonctionnement du système actuel;
- c) développer, avec la participation des groupements intéressés, des solutions de rechange plus efficaces aux services offerts actuellement aux établissements de soins de longue durée; et
- d) étudier la création d'un conseil d'administration indépendant provenant du secteur privé pour en surveiller l'exploitation, si on décide de la conserver, sous une forme ou une autre.

**6.8 Par conséquent, le comité recommande que les programmes pour la dose unitaire/mixtion intraveineuse soient adoptés comme système de prédilection pour la délivrance de médicaments dans les hôpitaux d'une certaine grosseur.**

**6.9 Par conséquent, le comité recommande en outre que, d'ici 1991, le ministère de la Santé de l'Ontario et l'Ontario Hospital Association déterminent la grosseur et les autres conditions pertinentes, et que les hôpitaux identifiés reçoivent des subventions pour se convertir au système de dose unitaire.**

## **Chapitre VII La prescription des médicaments**

Le rôle du médecin dans la prescription d'un médicament est examiné des points de vue tant théorique que pratique. Le septième chapitre traite de la prescription des médicaments, du rôle clé joué par les médecins en tant que prescripteurs, de l'éducation des médecins dans ce rôle et des moyens par lesquels la prescription des médicaments pourrait être améliorée.

On passe en revue des modèles d'information illustrant les facteurs qui influent sur les décisions des médecins et l'on recommande que toutes les parties intéressées à l'usage des produits de prescription en Ontario aient comme objectif une pharmacothérapie judicieuse. Le comité préconise également d'examiner la possibilité de mettre sur pied un centre ontarien pour l'étude et l'amélioration de la prescription des médicaments, dont le financement serait partagé par l'industrie et le ministère de la Santé.

Des discussions sur le consentement éclairé au traitement et sur le rôle du médecin, en tant que défenseur du patient ou gardien de la société, sont à l'origine de la recommandation selon laquelle les prescripteurs soient

responsables à l'égard de leurs patients, tandis que la profession médicale devrait jouer un rôle dans la protection des ressources de la société.

On se penche sur la question de l'éducation des médecins en ce qui a trait à la thérapeutique – dans les études de premier cycle et de deuxième et troisième cycles ainsi que dans l'éducation permanente des médecins. Le comité d'enquête conclut que les stratégies de prescription ne sont pas traitées adéquatement dans les cours de base en pharmacologie médicale et que la formation dans la façon de prescrire dépend d'une variété d'expériences, au moment de l'apprentissage. Pour combler cette lacune, le comité d'enquête recommande que des mesures soient prises dans toutes les écoles de médecine de l'Ontario : modifier les programmes pour mettre l'accent sur la bonne façon de prescrire; intégrer les sciences de base et les sciences cliniques, en particulier la pharmacologie et la pharmacothérapie; reconnaître les différences dans le type de morbidité rencontré dans les hôpitaux d'enseignement et dans les centres de médecine communautaire; accorder une plus grande importance à l'évaluation critique des produits pharmaceutiques et aux besoins en pharmacothérapie des personnes âgées en matière de traitement.

Au niveau des deuxième et troisième cycles, les mesures recommandées concernent : l'examen régulier des aspects pharmacologiques de la thérapie; une meilleure intégration de la pharmacologie clinique dans tous les services, y compris les blocs de chirurgie; l'amélioration des méthodes de vérification quant à l'utilisation des produits de prescription; et une expérience particulière en gériatrie, au moment de l'internat et de la résidence.

Afin que les pourvoyeurs de soins aient continuellement accès à de l'information susceptible de promouvoir la façon judicieuse

de prescrire, le comité recommande : des programmes efficaces en formation médicale permanente; des études d'observation post-marketing innovatrices impliquant un grand nombre de médecins de famille; et le développement de programmes pilotes permettant d'étudier l'utilisation des médicaments.

Après avoir analysé ce que pensent les médecins de leur éducation en tant que préparation à la prescription de médicaments, ainsi que les rôles joués par le gouvernement et les associations médicales, le comité recommande que la profession médicale développe des règles de conduite en matière de prescription.

Le comité a formulé également les recommandations suivantes : une publication mise à jour régulièrement qui renfermerait des règles de conduite pour la prescription basées sur des renseignements objectifs quant aux produits pharmaceutiques de prédilection; restreindre l'usage des médicaments particulièrement coûteux lorsque des produits de rechange plus économiques sont disponibles; poursuivre le développement et l'usage de formulaires limités pour les hôpitaux; la prolongation de la méthode du formulaire limité pour les cliniques de groupe et autres établissements de soins de santé; l'utilisation des noms d'appellation commune dans la rédaction des ordonnances et l'étiquetage des médicaments; et la promotion de révisions régulières et cohérentes des pharmacothérapies. En ce qui concerne les rapports entre les fabricants et les médecins, le comité recommande la mise sur pied de projets pilotes pour mettre à l'épreuve des façon impartiales et non axées sur la marque de commerce de faire des présentations sur les produits, et le développement de règles d'éthique pour guider les rapports entre les médecins et l'industrie. Le chapitre se termine sur une discussion et des recommandations ayant trait à : la mise sur pied d'un département de pharmacologie clinique dans chaque école de médecine en Ontario; des mécanismes destinés à renforcer les liens entre les

médecins et les pharmaciens; la création d'un service d'information sur les médicaments chargé de faire l'évaluation des médicaments très coûteux; et une révision des produits grand public inscrits dans le Formulaire, afin de les classer parmi les médicaments à usage restreint ou à usage général.

**7.1 Par conséquent, le comité recommande qu'en tant que partie intégrante d'une thérapie optimale, la pharmacothérapie judicieuse devrait être l'objectif de toutes les parties s'intéressant à l'usage des produits de prescription en Ontario.**

**7.2 Par conséquent, le comité recommande que le ministère de la Santé invite l'industrie pharmaceutique à examiner conjointement la possibilité de partager le financement d'un centre ontarien pour l'étude de la prescription médicamenteuse. Il serait rattaché à un centre des sciences de la santé et aurait des liens avec des médecins praticiens, par l'entremise du Collège royal des médecins et chirurgiens du Canada, du Collège des médecins de famille du Canada et de l'Association des médecins de l'Ontario, ainsi qu'avec les départements de pharmacologie clinique qui, selon nous, devraient être créés dans chacune des facultés de médecine en Ontario. (Voir la recommandation 7.17.)**

**7.3 Par conséquent, le comité recommande au College of Physicians and Surgeons of Ontario et à l'Association des médecins de l'Ontario d'encourager les prescripteurs à se faire les défenseurs de leurs patients et à être responsables devant eux. D'autre part, la profession médicale a un rôle à jouer dans la protection des ressources de la société.**

**7.4 Par conséquent, le comité recommande que l'Association des médecins de l'Ontario et le College of Physicians and Surgeons of Ontario, avec la participation de l'Ontario Pharmacists' Association et de l'Ordre des**



pharmaciens de l'Ontario, étudient conjointement à quel point la quantité de médicaments prescrits dans une ordonnance est pertinente et émettent des lignes de conduite appropriées.

7.5 Par conséquent, le comité recommande au Council of Ontario Faculties of Medicine d'encourager chacune des écoles de médecine de l'Ontario à prendre les mesures suivantes en matière d'enseignement :

- a) Des études pilotes pour déterminer l'efficacité des modifications apportées dans les programmes d'enseignement de premier cycle et de deuxième et troisième cycles mettant l'accent sur l'acquisition et le maintien de bonnes habitudes de prescription médicamenteuse;
- b) Une meilleure intégration des sciences de base et des sciences cliniques, en particulier l'intégration de la pharmacothérapie à la pharmacologie;
- c) Une meilleure reconnaissance par les départements de spécialités cliniques des différences quant aux modèles et aux types de morbidité rencontrés dans les hôpitaux d'enseignement et dans les centres de médecine communautaire;
- d) Une plus grande importance de l'évaluation critique des produits pharmaceutiques dans les programmes d'enseignement de la médecine; et
- e) Une plus grande importance des besoins particuliers des personnes âgées en matière de traitement de problèmes médicaux. (Voir aussi le chapitre 11)

7.6 Par conséquent, le comité recommande que les mesures en matière d'enseignement médical de deuxième et troisième cycle comprennent :

- a) L'examen régulier des aspects pharmacologiques de la thérapie;

b) Une meilleure intégration de la pharmacologie clinique dans tous les services, y compris les blocs de chirurgie;

c) L'amélioration des méthodes de vérification quant à l'utilisation des produits de prescription; (Voir également la révision sur l'utilisation médicamenteuse); et

d) Une expérience particulière en gériatrie, au moment de l'internat ou de la résidence.

7.7 Par conséquent, le comité recommande que:

- a) Le Council of Ontario Faculties of Medicine, l'Association des médecins de l'Ontario et le College of Physicians and Surgeons of Ontario soient invités, d'ici 1991, à développer des programmes en formation médicale permanente qui soient nouveaux, innovateurs et efficaces, afin d'encourager la participation d'un plus grand nombre de médecins; et
- b) Le Council of Ontario Faculties of Medicine, conjointement avec le Comité d'appréciation des médicaments et des thérapeutiques, l'Association canadienne de l'industrie du médicament, l'Association des fabricants de produits pharmaceutiques, Santé et Bien-être social Canada, l'Association pharmaceutique canadienne, et le ministère de la Santé de l'Ontario soient invités à développer, d'ici 1993, des études d'observation post-marketing innovatrices sur une diversité de préparations pharmaceutiques, tant des produits de marques de commerce que des produits d'appellation commune, et impliquant un grand nombre de médecins de famille.

7.8 Par conséquent, le comité recommande que la profession médicale développe, par l'entremise de ses nombreuses organisations, des règles de conduite pertinentes en matière de traitement.

7.9 Par conséquent, le comité recommande la publication du répertoire intitulé «Choice of Medications - 1990» et que celui-ci soit mis à la disposition, chaque année, de tous les médecins agréés et à toutes les pharmacies en Ontario. Cette publication devrait contenir des directives pour la prescription basées sur des renseignements objectifs concernant les produits pharmaceutiques préférés, y compris leurs indications, contre-indications, effets secondaires, la posologie recommandée et les coûts relatifs.

7.10 Par conséquent, le comité recommande que le ministère de la Santé continue d'être guidé par le Comité d'appréciation des médicaments et des thérapeutiques dans le développement du concept d'usage limité dans le Formulaire du Programme de médicaments gratuits de l'Ontario. (Voir aussi les recommandations 4.2 et 4.3.)

7.11 Par conséquent, le comité recommande que l'Ontario Hospital Association soit invitée à encourager le développement et l'usage de formulaires limités dans les hôpitaux.

7.12 Par conséquent, le comité recommande que le ministère de la Santé, l'Association des médecins de l'Ontario et l'Ontario Pharmacists' Association encouragent la prolongation de la méthode de formulaires limités pour les cliniques de groupe, les maisons de soins infirmiers, les foyers pour personnes âgées, les organisations de maintien de la santé et les organisations de médecine globale.

7.13 Par conséquent, le comité recommande qu'en Ontario, l'usage des noms d'appellation commune des produits pharmaceutiques soit encouragé dans la rédaction des ordonnances et l'étiquetage des médicaments, sauf lorsqu'il existe une raison spéciale d'utiliser un nom de marque de commerce.

7.14 Par conséquent, le comité recommande que le Council of Ontario Faculties of Medicine, le College of Physicians and Surgeons of Ontario et l'Association des médecins de l'Ontario soient invités à faire la promotion de révisions régulières, pertinentes et cohérentes aux pharmacothérapies.

7.15 Par conséquent, le comité recommande que, d'ici 1992, le ministère de la Santé mette sur pied des projets pilotes pour mettre à l'épreuve des façons impartiales de faire des présentations sur les produits en Ontario, d'après le modèle de Harvard. Ceci devrait être précédé par des consultations avec l'Ordre des pharmaciens de l'Ontario, l'Ontario Pharmacists' Association, le College of Physicians and Surgeons of Ontario, l'Association des médecins de l'Ontario et l'industrie pharmaceutique.

7.16 Par conséquent, le comité recommande que, d'ici 1991, le College of Physicians of Ontario, après avoir consulté l'Association des médecins de l'Ontario et l'industrie pharmaceutique, développe et publie des règles d'éthique pour guider les rapports entre les médecins et l'industrie, ces règles portant également sur la participation de l'industrie à l'éducation médicale permanente.

7.17 Par conséquent, le comité recommande que le ministère des Collèges et Universités soit invité à promouvoir et à financer la mise sur pied d'un département de pharmacologie clinique dans chaque école de médecine de l'Ontario. Ils devraient être étroitement rattachés au centre pour l'étude de la prescription médicalemente. (Voir la recommandation 7.2)

7.18 Par conséquent, le comité recommande que l'Association des médecins de l'Ontario, la Société canadienne des pharmaciens d'hôpitaux (section de l'Ontario) et l'Ontario

Pharmacists' Association soient invités à créer des mécanismes officiels, aux niveaux provincial et local, qui renforceront les liens professionnels sur les questions relatives à la consultation et la communication avec les patients, ainsi que sur d'autres questions d'intérêt commun. Nous suggérons de mettre l'accent sur la liaison au niveau communautaire, entre particuliers et dans des groupes.

**7.19** Par conséquent, le comité endosse la recommandation du groupe d'étude sur la consommation médicale et la prestation des soins médicaux (groupe d'étude Scott) pour la création du Conseil de l'Ontario sur l'évaluation de la technologie médicale, et recommande que parmi ses fonctions, cet organisme examine les nouveaux médicaments très coûteux.

**7.20** Par conséquent, le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques soit invité à réviser tous les produits grand public au titre du Régime de médicaments gratuits de l'Ontario, comme il le fait pour les autres produits de prescription, et que tous les produits grand public inscrits dans le formulaire soient classés parmi les médicaments à usage général ou à usage limité.

## Chapitre VIII Délivrance/administration

Un des principaux domaines du mandat du comité d'enquête a trait à la délivrance des médicaments et au rôle du personnage principal dans cette fonction—le pharmacien. Le chapitre huit, qui porte sur la délivrance des médicaments, fait l'objet du quatrième rapport intérimaire du comité d'enquête. Le comité est d'avis que les recommandations dans ce domaine, si elles sont adoptées, mèneront à une redéfinition souhaitable et de grande portée du rôle du pharmacien et que l'Ontario a la possibilité d'assumer, sous ce rapport, un rôle de chef de file à la fois à l'échelle nationale et internationale.

Dans l'élaboration des recommandations, le comité a tenu compte du fait que les responsabilités du pharmacien englobent deux fonctions principales : des activités cognitives axées sur le patient, par exemple la consultation avec les patients, les prescripteurs et autres professionnels de la santé, et des activités qui sont axées sur le produit, par exemple l'acquisition, l'entreposage, l'étiquetage, l'emballage et la délivrance des médicaments, ainsi que la tenue des dossiers. Les problèmes relatifs à ces deux fonctions sont reflétés dans le rapport.

Les conditions économiques de l'exercice de la pharmacie dans la communauté à l'heure actuelle risquent d'avoir un impact négatif sur la prestation de services axés sur le patient, du fait que le système de paiements est structuré de façon à rembourser les pharmaciens sur la base des médicaments délivrés, et non pas sur celle des services professionnels dispensés. Des stratégies s'imposent pour rémunérer la prestation de services souhaitables, axés sur le patient, tout en maintenant la fonction traditionnelle des pharmaciens, qui est de délivrer des médicaments. Le rapport examine également les facteurs qui mènent à des changements dans l'exercice de la pharmacie, comme les changements dans les attentes du public et des professionnels, le vieillissement de la population, les pressions en vue de freiner la hausse des coûts, la demande dépassant l'offre pour ce qui est des pharmaciens, l'augmentation de la spécialisation professionnelle, l'évolution de la technologie et les questions concernant le maintien de la compétence professionnelle.

Les recommandations relatives au produit ont trait à l'expansion du rôle du personnel auxiliaire non professionnel, des systèmes d'information qui donnent des renseignements sur les interactions médicamenteuses indésirables, les normes d'emballage et d'étiquetage conçues en fonction de la commodité pour le



consommateur, plus particulièrement pour ce qui a trait aux patients ayant des besoins spéciaux en matière d'information.

Les recommandations axées sur le patient portent sur l'éducation du public, en insistant particulièrement sur les personnes âgées; la nécessité des profils pharmacothérapeutiques, les «cartes à mémoire», l'accès du pharmacien aux diagnostics du patient, le remboursement des consultations avec le patient, l'expansion du rôle clinique des pharmaciens, les comités de pharmacothérapie dans la communauté et les recommandations traitant des changements dans les études de pharmacie. Ces derniers changements comprennent notamment une restructuration de la formation actuelle en pharmacie, des changements dans l'envergure de la Faculté de pharmacie de l'Université de Toronto, la création d'une nouvelle faculté de pharmacie, la création d'un programme de doctorat en pharmacie, l'enseignement en commun pour les étudiants des facultés de pharmacie et de médecine, ainsi que l'accent croissant sur la communication interprofessionnelle dans la formation des étudiants en médecine, en soins infirmiers et en pharmacie.

Le rôle des infirmiers est examiné en fonction des systèmes d'acquisition médicale «faciles pour les infirmiers» dans les établissements de soins de longue durée, des consultations aux patients, de la participation aux comités de pharmacothérapie et de thérapeutique et de l'éducation permanente, et en fonction des mécanismes de recherche de solution dans les cas de désaccord quant à la pertinence des thérapies. Des recommandations ont été formulées à cet effet.

Les autres discussions et recommandations ont trait aux pharmacies d'hôpitaux, aux soins à domicile, aux programmes de résidence en pharmacie dans les hôpitaux et à l'utilisation de médicaments à l'étude pour les essais cliniques. Le rôle des dispensateurs de soins à

domicile et autres soins de santé est envisagé du point de vue des besoins de ces dispensateurs et à la lumière des services disponibles.

**8.1 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario définisse clairement les rôles respectifs du personnel auxiliaire et des pharmaciens et qu'il s'assure que les aides effectuent les tâches techniques, axées sur le produit, tandis que les pharmaciens se concentrent sur les tâches axées sur le patient, par exemple surveiller la pharmacothérapie et donner des conseils sur les médicaments aux patients et à d'autres professionnels de la santé. Les stratégies utilisées pour en assurer l'application devraient être associées à la promulgation de normes en matière d'exercice et d'assurance de la compétence.**

**8.2 Par conséquent, le comité recommande que, d'ici la fin de 1992, le ministère de la Santé, l'Ordre des pharmaciens de l'Ontario et l'Ontario Pharmacists' Association établissent conjointement les exigences portant sur les systèmes de gestion par ordinateur et les directives qui en régissent l'usage, de façon à s'assurer l'accès optimal aux profils des patients et aux programmes relatifs aux interactions indésirables des médicaments. D'autre part, le comité recommande que l'Ordre des pharmaciens de l'Ontario établisse des directives régissant l'exercice en vue de mettre en oeuvre l'utilisation optimale de ce genre de système de gestion des données.**

**8.3 Par conséquent, le comité recommande que, d'ici la fin de 1990, des normes soient établies pour les produits pharmaceutiques présentés dans ce qu'on appelle des emballages «format délivrance» ou «emballage d'origine». Ces normes devraient assurer qu'aucun emballage d'origine délivré ne devrait créer d'incertitude ou de confusion, gêner les traitements individualisés,**

entraver l'interchangeabilité des produits pharmaceutiques (aux fins de l'interchangeabilité, les caractéristiques physiques des emballages ne devraient pas être considérés comme étant uniques), ni constituer un outil de commercialisation ou de promotion (la promotion auprès du public d'une certaine marque ne devrait pas être une caractéristique du graphisme ou de l'étiquetage). Par ailleurs, les emballages devraient obligatoirement répondre aux normes d'un emballage protège-enfants.

8.4 Le comité recommande en outre que le ministère de la Santé, en consultation avec les organismes intéressés appropriés, entame sans tarder des discussions avec la Direction générale de la protection de la santé et Bien-être social Canada pour établir ces normes.

8.5 Par conséquent, le comité recommande que d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario crée un groupe de travail ayant expressément pour but de réaliser l'expansion de la pratique consistant à fournir des étiquettes auxiliaires et d'autres renseignements imprimés sur les produits de prescription, ainsi que le renforcement verbal par le pharmacien à l'intention du patient. Ce groupe de travail devrait inclure un ou des représentants des consommateurs.

8.6 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario encourage la profession à porter une attention toute particulière aux besoins des patients handicapés visuels en utilisant des notices et un graphisme appropriés, à gros caractères, chaque fois que cela est possible dans la préparation de l'étiquetage d'un produit de prescription.

8.7 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario encourage l'utilisation d'étiquettes et d'autres instructions dans la langue que le patient connaît bien, le pharmacien ayant pour responsabilité de donner le renforcement approprié par voie verbale.

8.8 Par conséquent, le comité recommande que, d'ici la fin de 1990, le ministère de la Santé effectue une campagne d'éducation, conçue principalement à l'intention des personnes âgées, et recommandant aux patients de choisir une pharmacie pour y obtenir, dans la mesure du possible, tous les services de pharmacie.

8.9 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario réalise l'application de cette tendance volontaire par des règlements exigeant de toutes les pharmacies qu'elles maintiennent des profils pharmaceutiques des patients, conformément à des normes définies quant à leur teneur.

8.10 Par conséquent, le comité recommande que l'Ordre des pharmaciens de l'Ontario, l'Ontario Pharmacists' Association, le ministère de la Santé et d'autres parties intéressées travaillent diligemment à la mise au point de dossiers transférables concernant les dossiers pharmaceutiques des patients, par exemple sous forme de «cartes à mémoire».

8.11 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Association des médecins de l'Ontario, le College of Physicians and Surgeons of Ontario, le Collège royal des chirurgiens dentistes d'Ontario, l'Ontario Pharmacists' Association et l'Ordre des pharmaciens de l'Ontario élaborent des directives pour

s'assurer que le pharmacien, lorsque cela est approprié au point de vue clinique et avec le consentement du patient, ait accès au diagnostic du patient.

8.12 Par conséquent, le comité recommande que, d'ici la fin de 1990, le ministère de la Santé, en collaboration avec les organismes intéressés appropriés, par exemple l'Ontario Pharmacists' Association et l'Ordre des pharmaciens de l'Ontario, organise une campagne pour sensibiliser le public aux services auxquels on peut s'attendre de la part du pharmacien, en mettant l'accent sur ceux consistant à donner des renseignements sur l'usage approprié des médicaments.

8.13 Par conséquent, le comité recommande que l'Ordre des pharmaciens de l'Ontario exige que, d'ici la fin de 1991, toutes les pharmacies de l'Ontario aient un endroit convenable pour la consultation, où les patients peuvent discuter de leurs médicaments avec un pharmacien, et cela dans l'intimité et dans un confort relatif.

8.14 Le comité recommande en outre que les pharmaciens exercent davantage de contrôle sur la vente des médicaments en vente libre et que, d'ici la fin de 1991, l'Ordre des pharmaciens de l'Ontario exige que toutes les pharmacies de l'Ontario aient un rayon des produits professionnels, adjacent ou contigu à l'officine, où doivent se trouver tous les médicaments en vente libre. [Cette consigne n'inclut pas les médicaments de la liste «C», qui ne doivent pas être disponibles en libre choix.]

8.15 Par conséquent, le comité recommande que, d'ici la fin de 1991, l'Ordre des pharmaciens de l'Ontario exige l'utilisation, dans la pharmacie, d'enseignes et de matériel imprimé pour avertir le public de l'importance qu'il y a à consulter un pharmacien concernant l'emploi des

médicaments en vente libre, surtout lorsqu'on les prend en même temps que des produits de prescription.

8.16 Par conséquent, le comité recommande que, d'ici la fin de 1991, le ministère de la Santé, en collaboration avec l'Ontario Pharmacists' Association, établisse des projets pilotes pour examiner et évaluer des mécanismes de remboursement offerts à titre de solution de rechange qui rémunéreraient le fournisseur de services pharmaceutiques professionnels et qui seraient indépendants de la vente ou de la délivrance d'un médicament.

8.17 Par conséquent, le comité recommande que, d'ici la fin de 1992, le ministère de la Santé, conjointement avec l'Ontario Pharmacists' Association, l'Ordre des pharmaciens de l'Ontario et l'Ontario Hospital Association, crée un lien entre les dossiers pharmaceutiques des patients dans les pharmacies de la communauté et les pharmacies d'hôpital, et qu'ils s'assurent que les consultations qui ont lieu avant l'hospitalisation ou avant le renvoi à domicile du patient soulignent au patient l'importance d'un tel échange de renseignements.

8.18 Par conséquent, le comité recommande que le ministère de la santé, conjointement avec l'Ontario Hospital Association, l'Association des médecins de l'Ontario, l'Ontario Pharmacists' Association, la Société canadienne des pharmaciens d'hôpitaux (section de l'Ontario) et l'Ordre des pharmaciens de l'Ontario encouragent immédiatement l'expansion du rôle clinique des pharmaciens dans l'utilisation accrue des formulaires, de la consultation pharmacocinétique, de la surveillance de la pharmacothérapie et de l'intervention subséquente en cas de besoin.



8.19 Par conséquent, le comité recommande que, d'ici la fin de 1992, les ministères de la Santé et des Services sociaux et communautaires, en collaboration avec l'Association des médecins de l'Ontario, l'Association des maisons de soins infirmiers de l'Ontario, l'Ontario Association of Non Profit Homes and Services for Seniors, l'Ontario Pharmacists' Association et l'Ordre des pharmaciens de l'Ontario, créent des projets pilotes qui font appel aux services de comités communautaires de pharmacothérapie basés sur les modèles existants en établissement.

8.20 Par conséquent, le comité recommande que, d'ici la fin de 1990, le ministère de la Santé et l'Ordre des pharmaciens de l'Ontario s'assurent que l'on encourage, que l'on soutienne et que l'on coordonne les programmes d'information sur les médicaments et qu'on les étende à d'autres professionnels.

8.21 Par conséquent, le comité recommande que, d'ici l'année universitaire 1992, ou au cours de l'année où une nouvelle faculté de pharmacie entrera en fonctions (voir la recommandation 8.22), la Faculté de pharmacie de l'Université de Toronto réduise ses inscriptions au nombre pour lequel elle a été conçue.

8.22 Par conséquent, le comité recommande que, d'ici l'année universitaire 1992, le ministère des Collèges et Universités crée en Ontario une seconde faculté de pharmacie, dont le nombre d'étudiants inscrits serait à peu près équivalent au chiffre réduit de la faculté de Toronto. Il devrait s'agir d'un programme de cinq ans semblable à celui recommandé pour l'Université de Toronto (voir la recommandation 8.23), établi dans une université de l'Ontario possédant un programme de sciences de la santé qui comprend la médecine. Dans la décision de créer cette faculté, on devrait tenir compte du besoin de ces

services dans le Nord de l'Ontario, mais le comité croit que les avantages à ce que les facultés de médecine et de pharmacie se trouvent au même endroit ont plus de poids que les considérations géographiques.

8.23 Par conséquent, le comité recommande que, d'ici l'année universitaire 1991, l'Université de Toronto commence un programme d'études de pharmacie de premier cycle de cinq ans, afin de permettre une formation pratique plus structurée et un enseignement accru dans les domaines des communications, de la consultation avec les patients, de la thérapeutique, de l'information sur les médicaments, de la pathopsychologie et de la gériatrie.

8.24 Par conséquent, le comité recommande que le programme de stages pratiques offert aux étudiants et aux internes en pharmacie soit entièrement structuré et qu'il soit intégré au programme de cinq ans recommandé ci-dessus. (Voir la recommandation 8.23.)

8.25 Par conséquent, le comité recommande au ministère des Collèges et Universités que, au cours des deux prochaines années, un programme de doctorat en pharmacie soit créé dans une faculté de pharmacie appropriée d'une université de l'Ontario.

8.26 Par conséquent, le comité recommande que, d'ici l'année universitaire 1991, les facultés de médecine et de pharmacie de l'Université de Toronto enseignent conjointement les étudiants dans le domaine des services axés sur les patients, y compris le choix de la pharmacothérapie, les techniques de surveillance et la consultation avec les patients. Cette recommandation est également adressée au ministère des Collèges et Universités et au Council of Ontario Faculties of Medicine à titre d'exigence pour la création d'une faculté de pharmacie supplémentaire.

8.27 Par conséquent, le comité recommande que le ministère des Collèges et Universités prenne une décision concernant la planification d'un tel centre des sciences de la santé dans le Nord de l'Ontario.

8.28 Par conséquent, le comité recommande que, d'ici la fin de 1990, la Faculté de pharmacie de l'Université de Toronto révise son programme d'études en vue de mettre davantage l'accent sur les communications, la consultation avec les patients, la thérapeutique, l'information sur les médicaments, la pathophysiologie et la gériatrie. En même temps, l'Ordre des pharmaciens de l'Ontario devrait réviser ses exigences en matière d'éducation permanente, de façon à y inclure des cours de pharmacologie relatifs à la gériatrie et à la pédiatrie, de même que des cours sur l'information relative aux médicaments, la mixtion intraveineuse, la radiopharmacie et l'alimentation parentérale totale.

8.29 Par conséquent, le comité recommande que, d'ici l'année universitaire 1991, l'Université de Toronto et le Council of Ontario Universities' Health Science Faculties s'assurent que la formation des étudiants en médecine, en soins infirmiers et en pharmacie comprend un volet qui met l'accent, de façon appropriée, sur la nécessité de communiquer au patient l'importance de l'utilisation appropriée des médicaments.

8.30 Par conséquent, le comité recommande que, d'ici 1991, le ministère de la Santé, conjointement avec l'Ontario Hospital Association, l'Ontario Association of Non Profit Homes and Services for Seniors et l'Association des maisons de soins infirmiers de l'Ontario révisent et améliorent au besoin les systèmes d'acquisition, d'entreposage, de délivrance et d'administration des médicaments dans les établissements pour soins de longue durée.

8.31 Par conséquent, le comité recommande la création d'un comité interdisciplinaire, composé de représentants de l'Ordre des infirmières et infirmiers de l'Ontario, du College of Physicians and Surgeons of Ontario, et de l'Ordre des pharmaciens de l'Ontario, afin de déterminer le rôle approprié de la profession d'infirmier dans la consultation avec les patients.

8.32 Par conséquent, le comité recommande la participation des soins infirmiers aux comités sur la révision de l'utilisation médicamenteuse, la pharmacie et la thérapeutique.

8.33 Par conséquent, le comité recommande que :

- a) L'enseignement permanent des infirmiers concernant la pharmacothérapie optimale soit accru; et
- b) L'Ordre des infirmières et infirmiers de l'Ontario soit invité à réexaminer les programmes d'enseignement en soins infirmiers pour s'assurer qu'ils comprennent des connaissances suffisantes en thérapeutique de base, afin de rendre plus significatives les études et les expériences après l'obtention du diplôme, de sorte que l'infirmier devienne un conseiller plus efficace en matière de traitement.

8.34 Par conséquent, le comité recommande que :

- a) L'Ordre des infirmières et infirmiers de l'Ontario précise et établit des normes pour l'enseignement de base et l'éducation permanente concernant la pharmacothérapie; et
- b) Le ministère de la Santé budgétise des fonds suffisants pour permettre à ses organisations de soins de santé de financer la participation d'infirmiers à des programmes d'éducation

permanente (c.-à-d. les défrayer de leurs dépenses d'éducation).

8.35 Par conséquent, le comité recommande que dans toute organisation où travaille un infirmier administrant des médicaments, il existe un mécanisme approprié pour la recherche de solution dans les cas de désaccord quant à la pertinence des thérapies.

8.36 Par conséquent, le comité recommande que, dans tous les établissements de soins de santé de l'Ontario, on crée des mécanismes pour bien renseigner les patients quant à leur plan de traitement avant leur renvoi à domicile. On doit accorder suffisamment de temps pour ceci; si cette tâche incombe aux infirmiers, il faudra prévoir des ressources adéquates pour leur assurer une formation appropriée et permanente concernant la pharmacothérapie.

8.37 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario, la section de l'Ontario de la Société canadienne des pharmaciens d'hôpitaux et l'Ontario Hospital Association prennent des mesures pour s'assurer que toutes les pharmacies d'hôpitaux exigent des profils pharmaceutiques des patients, conformément à des normes définies quant à leur teneur.

8.38 Par conséquent, le comité recommande que le ministère de la Santé et l'Ontario Hospital Association révisent le raisonnement derrière la ligne de conduite concernant le remboursement des ordonnances au titre du Programme de médicaments gratuits de l'Ontario dispensés aux malades externes des hôpitaux.

8.39 Par conséquent, le comité recommande que d'ici 1991, le ministère de la Santé, en collaboration avec l'Ontario Hospital Association, crée des mécanismes

pour compenser adéquatement les hôpitaux offrant des services pharmaceutiques professionnels aux malades externes.

8.40 Par conséquent, le comité recommande que l'alimentation parentérale totale, les antibiotiques administrés par intraveineuse, les analgésiques et les autres programmes concernant les médicaments pour les soins à domiciles soient améliorés et élargis, grâce à un programme de remboursement d'encouragement devant être négocié d'ici 1991 par le ministère de la Santé, l'Ontario Hospital Association, l'Ontario Pharmacists' Association et d'autres parties en cause.

8.41 Par conséquent, le comité recommande que, d'ici 1991, le ministère de la Santé, ou tout autre organisme approprié chargé d'octroyer des subventions, fournisse les fonds nécessaires pour augmenter tant le traitement des résidents en pharmacie dans les hôpitaux que le nombre de postes disponibles pour ces résidents.

8.42 Par conséquent, le comité recommande que d'ici 1991, l'Ontario Hospital Association, l'Association des médecins de l'Ontario, le ministère de la Santé et la section de l'Ontario de la Société canadienne des pharmaciens d'hôpitaux révisent les mécanismes régissant l'utilisation des médicaments à l'étude pour des essais cliniques dans les hôpitaux, dans l'intention d'établir des normes et de trouver des moyens de limiter les coûts qui soient appropriés du point de vue moral.

8.43 Par conséquent, le comité recommande qu'une limite légale de responsabilité soit établie pour l'administration des médicaments, de sorte que les associations et les personnes à leur service soient déchargées, sous des conditions précises, de leur responsabilité quant à l'administration ou la surveillance des médicaments dans les établissements.



**8.44** Par conséquent, le comité recommande que des cours portant sur les qualifications requises par les professionnels de la santé pour administrer les médicaments et surveiller l'observance thérapeutique des patients en établissement soient développés et qu'ils soient offerts dans le cadre de programmes d'hygiène publique.

**8.45** Par conséquent, le comité recommande que les programmes prévoyant la surveillance de l'observance pharmacothérapeutique des patients et l'administration des médicaments, et les activités de rappel, soient favorisés et financés dans le cadre de programmes de santé communautaire et d'hygiène publique.

**8.46** Par conséquent, le comité recommande que les programmes de surveillance de l'observance pharmacothérapeutique soient inclus dans le cadre des programmes approuvés qui sont développés ou mis en oeuvre par les équipes communautaires d'évaluation, les hôpitaux de jour et les centres pour soins de jour.

## Chapitre IX L'utilisation médicamenteuse

Ce chapitre, qui porte sur les consommateurs et les soins pharmaceutiques, fait le résumé de données diverses, de manière à présenter un profil démographique des usagers des services de santé en Ontario.

Un examen de la protection au titre du Programme de médicaments gratuits de l'Ontario et au titre des régimes privés d'assurance-maladie révèle que certaines catégories de personnes éprouvent des problèmes d'accès particuliers aux médicaments dont elles ont besoin, notamment les personnes et les familles à faibles revenus qui ne reçoivent pas de prestations de vieillesse ou d'aide sociale, et les personnes qui encourent des frais

désastreux en médicaments. Le comité recommande de couvrir les frais de médicaments pour ces catégories de personnes, tout en imposant toutefois une quote-part à celles dont le revenu dépasse les niveaux d'aide sociale. Une seconde recommandation, qui découle d'un examen de l'élasticité de la demande lorsque les consommateurs doivent payer une partie de leurs frais de médicaments, consiste à faire payer aux prestataires du Programme de médicaments gratuits de l'Ontario qui ne reçoivent pas d'aide sociale une partie de chaque ordonnance, jusqu'à un maximum annuel de 250 \$.

Une révision de l'utilisation médicamenteuse—qui est en quelque sorte une assurance de la qualité susceptible d'améliorer la prescription médicamenteuse et, par conséquent, la santé du public—doit comprendre de l'information sur quatre éléments étroitement liés : le médicament (thérapie); le patient (diagnostic); le médecin (prescripteur); et la pharmacie (dossiers sur la délivrance). Selon le comité, une révision de l'utilisation systématique, si elle est effectuée correctement, empêchera également le gaspillage et fera réaliser des économies.

Le comité recommande aussi que la province finance un programme d'information sur les réactions indésirables aux médicaments. L'Association des médecins de l'Ontario offre un tel programme à titre de service public depuis 1981. Cependant, des contraintes économiques menacent maintenant la continuation de ce programme, et le comité d'enquête est d'avis que, comme il vaut la peine de le préserver, la province devrait prendre des mesures pour garantir sa survie.

Ce chapitre traite également de l'usage impropre des produits de prescription et de la toxicomanie. Le comité d'enquête a étudié les facteurs contribuant à un usage excessif, comme les niveaux d'utilisation, la demande des consommateurs et les attentes sociales,

ainsi que le rôle joué par les fabricants et les médecins. Il a également examiné l'usage illicite des produits de prescription; selon la Gendarmerie royale du Canada, la Police provinciale de l'Ontario et la Police de la communauté urbaine de Toronto, il s'agit d'un problème qui prend de l'ampleur.

Il faut instaurer d'énergiques programmes d'éducation mettant en cause le milieu scolaire, les médias, nos trois paliers de gouvernement, l'industrie, les travailleurs et les groupements communautaires pour éduquer le public sur les dangers de l'usage excessif des médicaments et la toxicomanie. Il est aussi recommandé que les trois paliers de gouvernement mettent sur pied les mécanismes nécessaires pour rendre la toxicomanie, y compris la consommation improprie de produits de prescription, aussi socialement indésirable que ne l'est devenue la cigarette.

Tenant pour acquis que la prévention est préférable au traitement, le comité d'enquête recommande que les ordonnances pour les somnifères, les sédatifs et les tranquillisants soient données pour la période la plus courte possible et que les contenants portent clairement, lorsqu'il y a lieu, le libellé «sans renouvellement». On devrait entreprendre des recherches sur les diverses méthodes pour réduire l'usage excessif de ces substances.

**9.1** Par conséquent, le comité recommande que les personnes à faibles revenus ou les personnes encourant des frais désastreux en médicaments, qui ne sont pas protégées par des régimes privés d'assurance-maladie, soient défrayées de leurs médicaments par l'entremise d'un régime fondé sur un examen des ressources provenant du revenu, compte tenu d'un ajustement pour le nombre de personnes à charge, conformément aux lignes de conduite de l'aide sociale, et que des co-paiements soient perçus des personnes et des familles dont les revenus dépassent les niveaux d'aide sociale.

**9.2** Par conséquent, le comité recommande que les prestataires du Programme de médicaments gratuits de l'Ontario qui ne reçoivent pas d'aide sociale soient tenus de participer aux coûts des ordonnances. Le partage des coûts prendrait la forme d'un montant forfaitaire ne dépassant pas 4 \$, à payer pour chaque ordonnance. Le maximum annuel à payer par le consommateur pour des produits de prescription serait fixé à 250 \$. Les frais de médicaments au-delà de ce montant seraient complètement couverts par le Programme de médicaments gratuits de l'Ontario.

**9.3** Par conséquent, le comité recommande que le ministère de la Santé, conjointement avec le Council of Ontario Faculties of Medicine, entreprenne le développement, d'ici 1992, de programmes pilotes pour la révision de l'utilisation médicamenteuse, qui pourront devenir un élément important de l'éducation médicale permanente. Ces programmes auraient pour objet d'identifier des moyens pratiques et efficaces d'améliorer la qualité de la prescription médicamenteuse et l'état de santé des patients. De tels projets devraient recevoir l'appui financier, à distance, de la province. (Voir aussi la recommandation 4.6.)

**9.4** Par conséquent, le comité recommande qu'un programme d'information sur les réactions indésirables aux médicaments en Ontario soit maintenu et qu'il reçoive l'assistance de la province.

**9.5** Par conséquent, le comité recommande que les gouvernements du Canada et de l'Ontario, ainsi que les municipalités, mettent sur pied les mécanismes nécessaires, adéquatement financés et soutenus, pour rendre la toxicomanie aussi socialement indésirable.

**9.6 Par conséquent, le comité recommande que l'Association des médecins de l'Ontario, le Collège des médecins de famille du Canada et la Fondation de la recherche sur la toxicomanie effectuent conjointement des recherches sur les diverses méthodes pour réduire l'usage excessif des somnifères, des sédatifs et des tranquillisants.**

**9.7 Que les produits pharmaceutiques et les autres thérapies médicamenteuses indiquées médicalement (comme les enzymes et les vitamines nécessaires) servant au traitement de la fibrose kystique soient subventionnés au titre du programme pertinent du ministère de la Santé.**

**9.8 Que les produits pharmaceutiques et autres fournitures médicales servant au traitement de la thalassémie soient subventionnés au titre du programme pertinent du ministère de la Santé.**

## Chapitre X Les thérapies de rechange

Bien que le comité n'ait pas été invité à examiner des solutions de rechange à la prescription médicamenteuse, un certain nombre de mémoires qui lui ont été présentés ont souligné cet aspect de la question. Il existe un vaste ensemble de documents d'origine professionnelle et profane sur les dangers d'une attitude selon laquelle il existe «une pilule pour chaque bobo».

Bien que le rapport ne tente pas de faire un examen systématique des solutions de rechange aux produits de prescription, il conclut qu'une telle étude, effectuée conformément aux normes scientifiques, serait méritoire. Parmi les domaines qui méritent un regard plus approfondi des spécialistes et des législateurs, on mentionne à titre d'exemple le rôle de la nutrition par rapport à la santé et la maladie.

Ce chapitre ne comprend pas de recommandations spécifiques, mais suggère :

- que le ministère de la Santé commande un examen critique de la documentation vaste mais largement anecdotique portant sur la pharmacologie nutritionnelle;
- qu'on accorde plus de soutien à l'intention des départements des sciences de la nutrition dans les facultés de médecine en Ontario et en vue d'études menées conjointement avec les départements cliniques appropriés;
- que soit convoquée une conférence générale des plus réputés cliniciens, scientifiques de la nutrition et médecins ayant de l'expérience dans l'application des thérapies nutritionnelles, en vue d'explorer les tout derniers développements dans ce domaine;
- qu'on organise des projets, après la révision de la documentation et la conférence générale, pour mettre en application les thérapies nutritionnelles les plus prometteuses; et
- qu'on examine les implications du traitement par la nutrition contenues dans les recommandations de la Révision des lois régissant les professions de la santé (rapport Schwartz).

## Chapitre XI La pharmacothérapie des personnes âgées

Les organes détériorés des personnes âgées n'acceptent pas les médicaments aussi bien que ceux des jeunes gens. Chez ce groupe, la médication pose un risque parce qu'il faut modifier les posologies pour tenir compte de l'absorption, de la distribution, du métabolisme, de l'élimination et de la réaction aux médicaments qui sont typiques à l'organisme d'une personne âgée.



Le Formulaire du Programme de médicaments gratuits de l'Ontario devrait comprendre une liste des médicaments appropriés aux personnes âgées. Le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques examine la disponibilité de formulations liquides de certains médicaments comme le fer, l'acétaminophène et autres au besoin.

La génération actuelle et celle qui avance en âge continueront vraisemblablement de souffrir de bon nombre de maladies chroniques pouvant être traitées par une pharmacothérapie judicieuse. Selon une étude commandée par le comité d'enquête, 80 p. 100 de toutes les réactions médicamenteuses indésirables sont attribuables à la prolongation de propriétés pharmacologiques connues et pourraient être évitées.

L'étude indique que les causes principales des réactions indésirables sont la polypharmacie, la médication faite soi-même, l'inobservance thérapeutique, l'entreposage incorrect, le manque de formation des médecins quant à la façon appropriée de prescrire des médicaments aux personnes âgées, les problèmes de surveillance des patients âgés, un double système de prescription dans les hôpitaux et dans le cadre des soins après le renvoi à domicile et la sensibilité accrue aux médicaments chez les personnes âgées. Pour faire face à ces problèmes, le comité a recommandé que les «cartes à mémoire» qui seront offertes pour faciliter l'utilisation, la surveillance et la révision des médicaments soient programmées de façon à permettre la détection rapide de problèmes de pharmacothérapie. En outre, le système de communication électronique recommandé aux pharmacies devrait être programmé de manière à tenir compte des problèmes spéciaux concernant la prescription médicamenteuse aux personnes âgées.

Les fabricants ont également un rôle important à jouer afin de s'assurer de la sûreté des

nouveaux médicaments. Lorsque cela est faisable, les résultats d'essais de médicaments qui accompagnent les demandes de permis et d'inscription devraient inclure des données provenant de personnes âgées. De plus, lorsque cela est pertinent, les fabricants devraient fournir des données et des recommandations en vue de la prescription aux personnes âgées. On devrait demander aux facultés de médecine qui commanditent des essais de médicaments d'inclure des sujets âgés.

Comme les personnes âgées sont davantage enclines à souffrir de maladies multiples, elles sont particulièrement susceptibles de subir des réactions indésirables causées par l'interaction médicamenteuse, surtout si plusieurs prescripteurs ne sont pas au courant des autres médicaments que prend un patient.

Pour faire face à ce problème, le comité a recommandé que : les personnes âgées se choisissent un médecin personnel et n'en changent pas; les spécialistes et les cliniques d'hôpitaux informent le médecin de famille du patient des modifications apportées au régime médicamenteux du patient; des règles de conduite soient établies pour faire en sorte que les médecins dispensateurs de soins primaires tiennent et mettent à jour une liste des médicaments pris par un patient âgé; les médecins soient encouragés à recommander que les patients ayant un régime médicamenteux complexe apportent avec eux tous leurs médicaments à chaque visite à un médecin ou à l'hôpital.

Pour que les médecins et autres dispensateurs de soins de santé aient la formation voulue pour s'occuper des personnes âgées, le comité demande que les facultés de médecine révisent leurs programmes d'enseignement pour s'assurer qu'elles offrent l'enseignement et l'expérience nécessaires pour la prescription médicamenteuse aux personnes âgées, et que les programmes de formation de deuxième et troisième cycles en médecine

familiale et dans les spécialités comprennent des rotations spécifiques en médecine gériatrique, dont une expérience supervisée en pharmacothérapie. En outre, l'Association des médecins de l'Ontario, le Collège royal des médecins et chirurgiens du Canada et le Collège des médecins de famille du Canada sont invités à examiner les objectifs et les initiatives dans le domaine de l'éducation en ce qui a trait à la pharmacothérapie pour les personnes âgées.

Le chapitre se termine sur une recommandation à l'effet que tous les hôpitaux pour soins aigus et les établissements pour soins gériatriques de longue durée mettent sur pied des systèmes en vue de surveiller la pharmacothérapie des patients âgés.

**11.1** Par conséquent, le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques soit invité à examiner de façon spécifique la disponibilité de formulations liquides ou autres de certains médicaments, comme le fer et l'acétaminophène, à l'intention des personnes qui ont de la difficulté à avaler ou à prendre des médicaments sous forme solide.

**11.2** Par conséquent, le comité recommande que les cartes à mémoire, qui seront offertes pour faciliter l'usage, la surveillance et la révision des médicaments (voir la recommandation 8.10), soient programmées de manière à permettre la détection rapide de problèmes de pharmacothérapie (p. ex. des interactions médicamenteuses). Le système de communication électronique recommandé à toutes les pharmacies (voir la recommandation 8.2) devrait aussi être programmé pour tenir compte des problèmes spéciaux concernant la prescription médicamenteuse aux personnes âgées.

**11.3** Par conséquent, le comité recommande que la Direction générale de la

protection de la santé du gouvernement fédéral et le Comité d'appréciation des médicaments et des thérapeutiques de l'Ontario :

a) soient invités à encourager les fabricants à faire en sorte que, lorsque cela est possible et pertinent, les résultats d'essais de médicaments qui accompagnent les demandes de permis et d'inscription incluent des données provenant de personnes âgées, afin que la sûreté et la l'efficacité du médicament puissent être déterminées pour ce groupe. De même, les facultés de médecine ontariennes qui commanditent des essais de médicaments devraient être invitées à inclure des sujets gés lorsque cela est possible et pertinent; et

b) soient invités à exiger des fabricants de produits pharmaceutiques qu'ils fournissent des données et des recommandations spécifiques en vue de la prescription aux personnes âgées, lorsque cela est pertinent.

**11.4** Par conséquent, le comité recommande que :

a) Le ministère de la Santé, sur l'avis d'organismes pour les personnes âgées, développe des lignes de conduite et une campagne d'information dans le but d'amener, d'ici 1994, tous les patients, et surtout les personnes âgées, à se choisir un médecin personnel et à ne pas en changer.

b) L'Association des médecins de l'Ontario, l'Ontario Hospital Association et le College of Physicians and Surgeons of Ontario établissent d'ici 1992 des lignes de conduite pour assurer que les spécialistes et les cliniques d'hôpitaux informent méticuleusement et rapidement le médecin de famille d'un patient de tout changement suggéré à son régime médicamenteux.

c) Le College of Physicians and Surgeons of Ontario, le Collège des médecins de famille du Canada et l'Association des médecins de l'Ontario établissent, d'ici 1992, des lignes de conduite pour amener les médecins qui dispensent des soins primaires à tenir et à mettre à jour régulièrement une liste des médicaments pris par un patient âgé. Cette information devrait être partagée avec les autres professionnels prenant soin du patient.

d) L'Association des médecins de l'Ontario et l'Ontario Hospital Association, conjointement avec des organisations pour les personnes âgées, établissent d'ici 1991 des règles de conduite pour communiquer aux médecins la nécessité d'exiger des patients ayant un régime médicamenteux complexe qu'ils apportent avec eux tous leurs médicaments à chaque visite à un médecin ou à l'hôpital.

11.5 Par conséquent, le comité recommande que, d'ici 1992, le College of Physicians and Surgeons of Ontario, le Collège royal des chirurgiens dentistes de l'Ontario et l'Ontario Medical Association élaborent des lignes directrices pour que les ordonnances pour les somnifères, les sédatifs et les tranquillisants soient données pour la période la plus courte possible et que les contenants portent clairement le libellé «sans renouvellement» à moins d'une indication clinique contraire.

11.6 Par conséquent, le comité recommande que toutes les facultés de médecine de l'Ontario soient priées de réviser leurs programmes d'enseignement aux niveaux des premier, deuxième et troisième cycles, d'ici le 1<sup>er</sup> juin 1992, pour s'assurer que :

a) elles offrent l'enseignement et l'expérience nécessaires pour la prescription de médicaments aux personnes âgées, en soulignant les différences par rapport aux jeunes patients; et

b) tous les programmes de formation de deuxième et troisième cycles en médecine familiale et dans les spécialités comprennent des rotations spécifiques en médecine gériatrique, dont une expérience supervisée en pharmacothérapie, dans des établissements pour soins ambulatoires et de longue durée ainsi que dans des établissements pour soins aigus.

11.7 Par conséquent, le comité recommande que l'Association des médecins de l'Ontario soit invitée à réviser, d'ici le 1<sup>er</sup> janvier 1992, les cours d'éducation permanente offerts aux médecins ontariens, en ce qui concerne tous les aspects de la médecine gériatrique et de la pharmacothérapie pour les personnes âgées, afin de déterminer s'ils sont adéquats. L'Association des médecins de l'Ontario, en collaboration avec les facultés de médecine ontariennes, devrait être invitée à s'assurer que les lacunes sont comblées, de sorte que les médecins ontariens puissent mettre facilement et régulièrement à jour leurs connaissances et leurs compétences concernant les soins aux personnes âgées et la prescription de médicaments pour elles.

11.8 Par conséquent, le comité recommande que le Collège royal des médecins et chirurgiens du Canada et le Collège des médecins de famille du Canada soient invités à réviser leurs objectifs en éducation et leurs exigences concernant l'enseignement médical en gériatrie et la pharmacothérapie des personnes âgées.

11.9 Par conséquent, le comité recommande que le ministère de la Santé, conjointement avec l'Ontario Hospital Association, l'Ontario Association of Non Profit Homes and Services for Seniors et l'Association des maisons de soins infirmiers de l'Ontario, exige que, d'ici le 1<sup>er</sup> juillet 1992, tous les hôpitaux pour soins aigus et les établissements pour soins gériatriques



**triques de longue durée mettent sur pied des systèmes pertinents pour surveiller la pharmacothérapie des patients âgés.**

## **Chapitre XII Conclusion et recommandations**

Le dernier chapitre conclut que les Ontariens et Ontariennes reçoivent généralement un excellent traitement en ce qui concerne les produits de prescription et traite brièvement des problèmes qui ont été identifiés. Les recommandations sont définies en fonction de deux catégories : celles visant à améliorer la qualité du traitement mettant en cause des produits de prescription et celles visant à améliorer l'accès aux médicaments requis.

Un examen des incidences financières des diverses recommandations se rapportant au Programme de médicaments gratuits de l'Ontario révèle que, selon des prévisions à moyenne portée, la mise en oeuvre de toutes les recommandations représenterait des coûts supplémentaires d'environ 95 000 000 \$ et ferait économiser 195 500 000 \$, soit une économie nette d'environ 100 000 000 \$ par année. Ceci est l'équivalent d'une réduction de 15 p. 100 du coût annuel du programme.

En ce qui concerne les répercussions financières des autres recommandations, il ressort de cette section que les modifications proposées au Comité d'appréciation des médicaments et des thérapeutiques et à la formation des pharmaciens représenteraient des sommes additionnelles d'environ 5 300 000 \$ par année.

Il est impossible d'évaluer les incidences financières de plusieurs autres catégories de recommandations. Le chapitre se conclut par une liste des recommandations contenues dans le rapport.



# Contents

## Chapter I Introduction

1.1 Availability, Access and Cost Effectiveness .....	1
1.2 Mandate of the Inquiry .....	2
1.3 Process and Procedure .....	2

## Chapter II Objectives of the Inquiry—Optimal Drug Therapy

2.1 Optimal Therapy .....	5
2.2 Drugs and the Health Care System .....	6
2.3 The Appropriate Role of Government .....	8
2.4 Assuring Drug Quality .....	9
2.5 Assuring Appropriate Access .....	10
2.6 Assuring Affordability .....	11

## Chapter III Prescription Drug Programs in Ontario

3.1 Origin and Growth of Drug Benefit Programs .....	13
3.1.1 Access to Prescription Drugs in Ontario .....	13
3.1.2 Quality and Cost of Prescription Drugs in Ontario .....	14
3.1.2.1 PARCOST .....	15
3.1.2.2 Amendments to the Pharmacy Act .....	16
3.2 The Introduction of the ODB Program .....	17
3.2.1 The Price-Spread .....	18
3.2.2 Bills 54 and 55 .....	19
3.3 Current Situation .....	21
3.3.1 Current MOH Drug Programs .....	21
3.3.1.1 ODB Program .....	24
3.3.1.2 Expenditure Profile of the ODB Program .....	25
3.3.2 Private Drug Insurance Plans .....	26
3.3.3 Ministry of Community and Social Services .....	27
3.4 Other Provincial Prescription Drug Plans .....	27
3.4.1 Eligibility .....	28

3.4.2 Beneficiary Cost-sharing .....	28
3.4.3 Benefits .....	28
3.4.4 Product Selection .....	28
3.4.5 Administration .....	28
3.4.6 Current and Future Trends .....	29
3.4.6.1 Nova Scotia .....	29
3.4.6.2 New Brunswick .....	29
3.4.6.3 British Columbia .....	31
3.4.6.4 Saskatchewan .....	31
Appendix 3.1 Federal and Provincial Initiatives in the Prescription Drug Marketplace .....	32

## Chapter IV

### The Formulary and the DQTC

4.1 Drug Quality & Therapeutics Committee (DQTC) .....	33
4.1.1 Ontario Drug Benefit Formulary (ODBF) .....	33
4.1.2 The Formulary .....	34
4.1.3 Continuation of the Formulary .....	35
4.1.4 Option 1-Elimination of the Formulary .....	36
4.1.5 Option 2-Modifying the Formulary .....	37
4.1.6 Recommendations with Respect to the Formulary .....	37
4.1.7 The Process .....	39
4.2 DQTC .....	41
4.2.1 Composition and Mandate .....	41
4.2.2 Recommendations with Respect to the DQTC .....	42
4.3 Special Authorizations .....	43
4.4 Generic Drug Product Substitution .....	46
4.4.1 Interchangeability—Product Selection .....	48

## Chapter V

### Acquisition of Drugs

5.1 Role of Manufacturers .....	51
5.1.1 Structure of the Manufacturing Industry in Canada .....	51
5.1.2 Federal Regulation and Influence on Market Structure .....	55
5.1.2.1 Health Protection Branch .....	55
5.1.2.2 Patent Legislation .....	57
5.1.2.3 Patented Medicines Prices Review Board .....	58
5.1.3 Provincial Regulation and its Influence on Market Structure .....	59
5.1.4 Economic Influence .....	64
5.1.4.1 Investment .....	64
5.1.4.2 Research and Development .....	66



<b>5.1.5 Advertising, Promotion and Education .....</b>	<b>67</b>
5.1.5.1 Single-source Products .....	67
5.1.5.2 Multiple-source Products .....	71
<b>5.2 Hospital Purchasing Plans .....</b>	<b>71</b>
<b>5.3 Third-Party (Private) Insurers .....</b>	<b>74</b>

## Chapter VI Distribution of Drugs

<b>6.1 Role of Wholesale Drug Distributors .....</b>	<b>77</b>
6.1.1 Overview .....	77
6.1.2 Current Situation .....	77
6.1.3 Principles .....	78
6.1.4 Proposed Solutions .....	79
6.1.5 Issues and Recommendations .....	80
<b>6.2 Ontario Government Pharmacy and Medical Supply Services .....</b>	<b>85</b>
<b>6.3 Hospital Unit Dose .....</b>	<b>89</b>

## Chapter VII The Prescribing of Drugs

<b>7.1. Role of the Prescriber .....</b>	<b>91</b>
7.1.1 Informed Consent for Treatment—The Drug Information Dilemma .....	96
7.1.1.1 The Physician: Patient Advocate or Gatekeeper for Society? .....	97
7.1.1.2 The Quantities of Drug Prescribed .....	98
7.1.2 The Ontario Situation .....	99
7.1.2.1 Attitudes of Ontario Physicians to their .....	101
Education “as a preparation for prescribing drugs”	
7.1.3 Education of Physicians for Pharmacotherapy .....	102
7.1.3.1 Undergraduate Education for Pharmacotherapy .....	103
7.1.3.2 Internship and Residency Education for Pharmacotherapy .....	104
7.1.3.3 Continuing Medical Education .....	104
<b>7.2 The Role of Government and Medical Associations .....</b>	<b>106</b>
7.2.1 Appropriate Guides to Treatment .....	106
7.2.1.1 Guideline for Guidelines: .....	107
7.2.2 “Choice of Medications—Ontario 1990” .....	108
7.2.3 Restricted Use of Expensive Medications .....	108
7.2.4 Restricted Hospital Formularies .....	109
7.2.5 Restricted Formularies Out of Hospital .....	109
7.2.6 Drug Names .....	109
7.2.7 Treatment Reviews .....	110
7.2.8 Detailing .....	111
7.2.9 Guidelines for Industry .....	111
7.2.10 Clinical Pharmacologists .....	112
7.2.11 Prescriber/Pharmacist Relationships .....	113

<b>7.3 Hospital Formulary Committees .....</b>	<b>114</b>
<b>7.4 Non-Prescription Medications .....</b>	<b>116</b>
7.4.1 Over-the-counter Drugs and Drug Benefit Programs .....	117

## Chapter VIII Dispensing/Administration

<b>8.1 The Role of the Pharmacist .....</b>	<b>119</b>
8.1.1 Introduction .....	119
8.1.2 Overview .....	120
8.1.3 Factors Leading to Change .....	120
8.1.3.1 Public Expectations .....	120
8.1.3.2 Patient Patterns—Demographics .....	121
8.1.3.3 Cost Containment .....	121
8.1.3.4 Human Resources .....	121
8.1.3.5 New Drugs, Systems and Specialization .....	121
8.1.3.6 Technology .....	121
8.1.3.7 Professional Expectations .....	122
8.1.3.8 Competence .....	122
8.1.4 Issues and Recommendations .....	122
8.1.4.1 Product-Oriented Responsibilities .....	122
8.1.4.2 Patient-Oriented Responsibilities .....	124
8.1.4.3 Human Resources and Education .....	128
<b>8.2 Role of the Nurse .....</b>	<b>131</b>
8.2.1 Use of Human Resources .....	131
8.2.2 Counselling .....	132
8.2.3 Education .....	132
8.2.4 Institutions .....	133
<b>8.3 Hospital Pharmacy .....</b>	<b>134</b>
8.3.1 Out-Patient Services .....	135
8.3.2 Home Care Services .....	135
8.3.3 Hospital Pharmacy Residency Programs .....	135
8.3.4 Investigational Drug Use for Clinical Trials .....	136
<b>8.4 Role of Home Care and Other Health Care Workers .....</b>	<b>136</b>
8.4.1 Needs of Caregivers .....	136
8.4.2 Services Available .....	137

## Chapter IX Utilization

<b>9.1 Role of the Consumer .....</b>	<b>141</b>
9.1.1 Introduction—a Demographic Profile .....	141
9.1.1.1 A Health Profile of Ontario .....	142
9.1.1.2 Patterns of Mortality .....	142
9.1.2 Health Problems in the Community .....	143

<b>9.1.3 The Uses of Health Services</b>	<b>144</b>
9.1.3.1 Institutional Care	144
9.1.3.2 Professional Services	145
9.1.3.3 Drugs and Appliances	145
9.1.3.4 Other Health Expenses	145
9.1.3.5 The Uses of Health Services and Drugs in the Community	145
<b>9.1.4 The Burden of Ill Health</b>	<b>146</b>
<b>9.1.5 Ontario Drug Benefit Program—Use and Access</b>	<b>148</b>
9.1.5.1 The Growth and Use of the Ontario Drug Benefit Plan	148
9.1.5.2 Relative Importance of Components	149
to Overall Increases in Program Costs	
9.1.5.3 Use of ODB by Type of Beneficiary	149
9.1.5.4 The Projected Growth in the Numbers of Elderly	150
<b>9.1.6 Access to Other Drug Plans in Ontario</b>	<b>150</b>
9.1.6.1 Coverage by Private Insurance	150
9.1.6.2 Identifying Problems in Coverage	151
9.1.6.3 Strategies for Extending Coverage	153
9.1.6.4 Drug Plan Coverage and Cost-sharing	154
9.1.6.5 Coverage: A Summary of Options	156
<b>9.1.7 Informed Consumer Choice</b>	<b>157</b>
9.1.7.1 Self-care	157
9.1.7.2 Professional Care	158
9.1.7.3 Education and Information about Drugs	158
<b>9.2 Drug Utilization Review</b>	<b>160</b>
<b>9.3 Adverse Drug Reaction Reporting Program</b>	<b>161</b>
<b>9.4 Misuse and Abuse of Prescription Medications</b>	<b>163</b>
9.4.1 Mood-altering Drugs	163
9.4.2 Dependence on Drugs	164
9.4.3 Factors Contributing to Abuse	164
9.4.3.1 Levels of Use	164
9.4.3.2 Consumer Demand and Social Expectations	165
9.4.3.3 Pharmaceutical Manufacturers	165
9.4.3.4 Physician Prescribing	166
9.4.4 Illegal Use of Prescription Drugs	166
9.4.4.1 Prescription Forgery and Fraud	168
9.4.4.2 Prescription Drug Addiction	168
<b>9.5 Nursing Homes and Homes for the Aged</b>	<b>169</b>
<b>9.6 Special High Risk Groups</b>	<b>172</b>
9.6.1 Cystic Fibrosis and Thalassemia	172
9.6.2 Psychiatric Patients	173

## Chapter X Alternative Therapies

<b>10.1 Alternatives to Prescription Drug Products</b>	<b>175</b>
--	------------



## Chapter XI Pharmacotherapy for the Elderly

<b>11.1 Special Problems of the Elderly .....</b>	<b>181</b>
11.1.1 General Principles Underlying the Pharmacotherapy of the Elderly .....	181
11.1.2 Special Product Listing Needs of the Elderly .....	182
<b>11.2 Drug Utilization, Monitoring and Review .....</b>	<b>182</b>
11.2.1 Prescription Drug Addiction and the Elderly .....	186
<b>11.3 Education of Physicians and Other Health Care Providers .....</b>	<b>187</b>
<b>11.4 Hospitalization/Institutionalization of the Elderly .....</b>	<b>188</b>

## Chapter XII Conclusions and Recommendations

<b>12.1 Issues Raised by the Committee .....</b>	<b>191</b>
<b>12.2 Estimating the Costs and Savings of the Recommendations of the Inquiry .....</b>	<b>193</b>
12.2.1 Expenditures of the Ontario Drug Benefit Plan .....	193
12.2.2 Estimating the Impact of the Recommendations .....	193
on the Costs of the Ontario Drug Benefit Program	
12.2.2.1 Elimination of Special Authorizations .....	193
12.2.2.2 Constraining the Price of Prescribed Drugs .....	194
12.2.2.3 Distribution Costs .....	194
12.2.2.4 Prescription Renewals .....	194
12.2.2.5 Add Low Income and Disabled Persons to ODB .....	194
12.2.3 Economic Impact of Other Recommendations .....	195
<b>12.3 Conclusion .....</b>	<b>196</b>
<b>12.4 Summary of Recommendations .....</b>	<b>196</b>

## Annex I

<b>Committee Members and Inquiry Staff .....</b>	<b>229</b>
--	------------

## Annex II

<b>Alphabetical List of Briefs/Presentations .....</b>	<b>233</b>
--	------------



## Chapter I

### Introduction

*The Pharmaceutical Inquiry of Ontario was established on May 26, 1988, by Order in Council pursuant to Section 9 of the Ministry of Health Act, R.S.O. 1980, Chapter 280, to examine the role and influence of the government of Ontario with respect to prescription drugs.*

#### 1.1 Availability, Access and Cost Effectiveness

In addressing the broad terms of reference, which are set out fully below, the Inquiry recognized that not all matters pertaining to the acquisition, distribution, prescribing, dispensing and use of prescription drugs in Ontario could be investigated in depth during its 22 month mandate. Hence, attention has been focused on those factors that assure that public funds and the influence of the government are applied so as to:

- promote the availability of high quality pharmaceutical products and optimal drug treatment for the people of Ontario;
- facilitate appropriate access to drug treatment for all those who need it; and
- achieve cost effectiveness.

These objectives are discussed in greater detail in chapter 2 of this report, following a description of the process and procedures adopted by the Inquiry and a statement of the place of prescription drugs in the overall health care system. Subsequent sections will review the history and present status of government drug programs and present our analysis of the problems that relate to the acquisition and distribution of pharmaceutical products in Ontario; discuss the activities of

the health professionals who prescribe, dispense and administer prescription drugs; and deal with factors that influence the use and misuse of prescription drugs by the public. Options for effective responses to these problems are presented and preferred courses of action are recommended.

Since this report is submitted to the Minister of Health and the government of Ontario which commissioned it, most of the recommendations are directed to the government for consideration and action. However, some address professional associations, statutory bodies that regulate the health professions in Ontario, health science faculties in Ontario universities, pharmaceutical manufacturers and distributors, and the public itself.

Inquiry members have been greatly encouraged by the active and constructive participation of interested groups and by the prompt and positive response of the Minister of Health to recommendations made in interim reports. We have reason to hope that the recommendations submitted in this final report will receive favourable consideration. We are convinced that their implementation will improve the quality of drug therapy in Ontario, will improve access to prescription drugs for all those who need them, and will help eliminate unnecessary public expenditures on prescription drug programs.

## 1.2 Mandate of the Inquiry

The members of the Committee were appointed individually by Order-in-Council and were originally directed to report to the Minister of Health of Ontario and the Premier's Council on Health Strategy by December 31, 1989. Subsequently, a report to the Premier's Council on Health Strategy on February 15, 1990 was requested, and the mandate of the Inquiry was extended to March 31, 1990. A brief summary of the background of the Committee members and the Inquiry staff is presented in annex 1 to this report.

The Committee's terms of reference were the following:

"The Committee shall undertake an inquiry into all aspects of the government's role and influence in the prescription drug marketplace. In doing so, the Committee will examine issues with respect to acquisition, distribution, dispensing and prescribing in government-funded drug programs.

"The Committee will develop options and recommendations for the continuance, modification or restructuring of government-funded drug programs.

"In conducting the Inquiry, the Committee may specifically examine the following:

- The current drug programs operated by the government; their past, present and future trends in relation to government objectives.
- The cost effectiveness of the acquisition, distribution and financing mechanisms employed by the government.
- The most effective ways to ensure quality of care and quality assurance of drugs under the Ontario Drug Benefit program.
- The impact of utilization of drugs on the health status of eligible recipients.

- The current criteria for eligibility for the government sponsored programs.
- The most effective ways to integrate education, manpower, research and development and other relevant factors into an overall drugs and therapeutics program."

## 1.3 Process and Procedure

During the course of its work, the Inquiry benefited from the assistance, advice and information readily provided by individual members of the public; organized consumer groups and associations; manufacturers and distributors; associations of health professionals and individual nurses, pharmacists and physicians; the Ontario professional regulatory bodies; Health and Welfare Canada; several Ontario and other provincial ministries; third-party insurers; health science faculties of Ontario universities and community colleges; police forces of all three levels of government; and many others.

Some of this advice came to us unsolicited, beginning on the day the Inquiry was announced; suggestions continue to be received as this report is being written. Much more information derives from the Inquiry's specific requests for advice from parties involved in the prescription drug system, from the pharmaceutical manufacturers to members of the public who actually use the drugs.

Public hearings were held in Chatham, Hamilton, Kingston, Kitchener/Waterloo, Ottawa, Sudbury, Thunder Bay and Toronto. More than 100 presentations were made during 18 days of hearings which took place in October and November, 1988. Their quality was generally excellent, reflecting a substantial amount of preparation and a high level of interest. Media coverage of the hearings was thorough.



The Inquiry also held some hearings for interested parties on specific issues and received supplementary briefs from many who made public presentations. Committee members and staff met with various experts, public officials, professionals and representatives of industry. The list of groups and individuals who made formal presentations constitutes annex II.

The Inquiry also reviewed current Ontario government drug programs, previous studies and reports conducted in Ontario and elsewhere, and relevant legislation in Canada and abroad, and commissioned several research projects to provide supplementary information. The full reports of these projects are found in volume II which contains the appendices and appropriate sections have been introduced in the body of this report.

Although the Inquiry was directed to report its findings and recommendations by December 31, 1989, — a date which was later extended — interim progress reports to the Minister of Health were expected. When information obtained by the Inquiry was believed to support recommendations for change that are in the public interest, these were submitted in the interim reports.

The first interim report of August, 1988, presented the focus, process and plans of the Inquiry. The second report, dated December, 1988, reported on the public hearings and made specific recommendations regarding the special authorization system and the need to extend access to life sustaining drug products for persons with cystic fibrosis and thalassemia, two special high risk groups which face extremely high drug costs. The third interim report of April, 1989, made recommendations regarding drug utilization review; the provision of impartial, up-to-date information and prescribing guidance to physicians; and broadening the mandate of the province's Drug Quality and Therapeutics Committee with respect to determining drug interchangeability. This report also addressed problems affecting the wholesale distribution system and initiated an intensive review of options for dealing with these problems. The fourth interim report of December, 1989 presented an in-depth analysis of the changing role of the pharmacist in our society, and made important recommendations that follow from this.

The findings and recommendations contained in the interim reports are included within the appropriate context of this report.



## Chapter II

### Objectives of the Inquiry — Optimal Drug Therapy

*It is the underlying assumption of this Inquiry that Ontarians should benefit from a system that will assure optimal drug therapy.*

#### 2.1 Optimal Therapy

Therapy must be clinically appropriate, accessible to all who need it and affordable. No one should be deprived of medically essential treatment because he or she cannot afford the drug costs. The present government supported programs, such as the Ontario Drug Benefit (ODB) program, have been of obvious advantage to eligible recipients—mainly low income Ontarians who would otherwise have had difficulty in obtaining necessary medications. The ready availability and rational use of prescription medication, which is the norm in this province, has contributed to improving both the quality and length of life of the people of Ontario. However, no system is perfect. The changes recommended in this report are designed to further reduce illness and disability, including adverse drug reactions, and to enhance health where possible.

We are aware that the rapidly escalating cost of the ODB program (see section 3.3) is a major reason for the establishment of the Inquiry, but wish to stress that the problem of cost must be kept in perspective. Expressed as a percentage of the gross provincial product, prescription drug related costs over the years look much less alarming, considering the

remarkable therapeutic advances that are occurring. Prescribed drugs consumed 0.35 per cent of Ontario's gross provincial product in 1975 and this had risen only to 0.52 per cent by 1985.<sup>1</sup> By comparison, physician services, which were 1.1 per cent in 1975, grew to 1.42 per cent in 1985, and hospital services changed from 2.84 per cent to 3.02 per cent. As can be seen, it is the relative rates of increase which are alarming, not the absolute amounts. Prescription drug costs are rising at a much higher rate than are the other major elements of the health care system.

It is hard to demonstrate in a large population that improved pharmacotherapy directly translates into better personal health, because of the many factors that determine health and illness. However, on an individual or small group basis this is often obvious. At the same time it has been established that inappropriate application of drug therapy may cause or aggravate illness and also wastes resources. This is clearly undesirable.

Therefore, the ideal goal is **optimal therapy**. This is not only very attractive, but we believe, attainable.

<sup>1</sup> Health and Welfare Canada. National Health Expenditures in Canada 1975-1985. Cat. No. H21-99/1985E, Ottawa, Nov. 1987. Information updated in February of 1990.



## 2.2 Drugs and the Health Care System

The healing power of certain natural (and, later, synthetic) chemical substances has been recognized since antiquity. Traditionally, medications have constituted an important treatment mode in the hands of physicians who, in most societies, have been the socially mandated healers of the sick. Indeed the name of the profession, medicine, is the same as the name traditionally applied to chemical substances used for the purpose of healing (medicines, medications). The primitive medicine man, and today's technologically sophisticated physician, are linked by their reliance on drugs to alleviate suffering and extend life.

In the modern era, pharmacology (the study of the effects of drugs) and pharmacotherapy (the application of drugs as healing agents) have remained central to the management of many of the illnesses that afflict individuals worldwide. Indeed, the discovery and development of a large variety of effective drugs by pharmacologists and the pharmaceutical industry worldwide, is one of the success stories of this century, having paralleled, and at times spearheaded, the development of modern technologically driven scientific medicine. Advances in the understanding of the physiological, biochemical and, recently, molecular basis of many diseases, have frequently led to the discovery of valuable new drugs. At other times the sequence has been reversed: the empirical discovery of new and useful therapeutic agents has preceded and has contributed to the understanding of the bodily processes that fail in certain diseases. The discovery of potent new preventive and therapeutic agents has revolutionized health care, and, in the process, improved the human

condition. This is a tribute to the many scientists—working in universities, in the innovative drug industry and in health care settings—who have discovered life-enhancing and-extending drugs, and to the institutions—private, public, commercial and therapeutic—which made this work possible.

As a result, modern health care without effective drugs is unthinkable. Although we often take their availability for granted, when drugs are scarce, as in conditions of disaster and war, we are reminded of the extent to which health, comfort and life depend upon them. This makes it understandable that society should be concerned about ensuring both the quality of drugs powerful enough to require professional prescription, and ready access by all who require them.

It is important to recognize that while drugs are a crucial component of the treatment of the sick and disabled, they are only a part of a complex health care system. Drugs are not treatments given in isolation; in 1988 the cost of prescription drugs accounted for approximately 5 per cent of the budget of the Ministry of Health (MOH) of Ontario.<sup>2</sup> Indeed, medical treatment in general, including drugs, is not an end in itself but a means to a desired outcome — the achievement, improvement and preservation of health. Therefore, it is valuable to examine briefly the relationships among health, illness and disease, and the way in which drug therapy can help.

Today, health is not defined merely as the absence of disease. More broadly, it is seen as “a positive concept emphasizing social and personal resources, as well as physical capacity”.<sup>3</sup> Disease, strictly speaking, is a narrow term that refers to an abnormality of the human organism which impairs or threatens to impair normal functioning and

<sup>2</sup> Ont. Ministry of Treasury and Economics, *Economic Outlook and Fiscal Review: Ontario 1988*, p.96.

<sup>3</sup> World Health Organization. Quoted by J.R. Evans, chairman, in *Toward a Shared Direction for Health in Ontario: Report of the Ontario Health Review Panel*, Toronto, Ontario, June 1987.

may even pose a threat to life. Illness is a broader term that refers to a subjective state of feeling unwell which is frequently (but not always) associated with a specific disease. Health and illness are on a continuum and can be thought of as incompatible with each other. By contrast, a disease may be present even when the individual feels healthy (as, for example, in an early stage of diabetes, arteriosclerosis or cancer).

A person usually visits a physician because he or she feels ill, is afraid of having a disease, and/or seeks relief from unpleasant symptoms. The physician attempts to discover why the person feels ill, which includes identifying or ruling out the presence of disease. Having done this, the physician next attempts to help the person regain health, that is, to eliminate the feeling of illness to the extent possible.

What role do drugs play in this process? To promote health is, of course, the ideal of all health care systems. This has been underscored by influential reports issued by federal ministers of Health (Lalonde, 1974, Epp 1986) and, more recently, reports to the Ontario Minister of Health (Evans 1987, Podborski 1987, Spasoff 1987). The maintenance of health is largely related to healthy lifestyles, the protection of the physical environment, and the availability of psychological and social supports. Drugs do not ordinarily have a place in this process. Disease states are the exception: persons who need chronic medication, for example enzyme or hormone replacements, are a small percentage of the population. Episodes of acute illness which require medication are also exceptional in the life of an individual. For example, an otherwise healthy person will only require antibiotics for a brief period to treat infection.

To preserve health for the longest possible period in the human life span requires the prevention of illness. Great strides have been made in this regard during the past century, largely by the implementation of public health

measures. These include immunization, improved nutrition, safety of water, food and air, and improvements in housing as well as general economic factors. Although prescription drugs sometimes do have a place in the primary prevention of illness, this is limited. For example, certain drugs and vaccines can protect persons who must work in environments where there is a risk of infection, such as malaria or hepatitis.

However, once a disease process has started, prevention of the full ravages of the disease involves rapid identification and arrest of the pathological process. Here is where the greatest strides have been made in personal health care by physicians and other health care professionals and here is where prescription drugs have the greatest impact.

If a disease process is diagnosed, it is likely that a drug can be prescribed that will arrest it, improve its symptoms or cure it. When a cure is not possible, drug therapy is often essential to keep us as healthy, comfortable and productive as the disease process allows. If no disease is discovered to account for the feelings of illness, it may still be possible to prescribe drugs that will make the person feel better or that will relieve symptoms or anxiety. However, in such circumstances, the drugs have a more restricted role to play.

Rehabilitation is the next task once the acute phase of the disease has been treated. Here, too, drugs can be helpful, though their role may be different than in the acute phase.

There is no place for prescription drugs as recreational agents. It is important to recognize that while drugs can be very useful in helping people cope with major stress, life problems are not solved by the use of chemicals.

To summarize, prescription drugs are most appropriately used in the treatment of disease states and for the short-term relief of

symptoms. Less often they are used in the prevention of further illness and as part of rehabilitation programs. Alternatives to drugs are preferable in the promotion and maintenance of health.

During the past 20 years, it has been the policy of the governments of Canada and all provinces to assure appropriate access to necessary medical treatment for all residents. The Canada Health Act (1984) has confirmed that provincial health plans must provide publicly administered, universal and comprehensive health care services, and all provinces and territories do so.

The means by which access to necessary prescription drugs is facilitated varies across Canada (see chapter 3). In Ontario, at present, all persons 65 years and older qualify for prescription drugs at no direct cost to themselves, as do persons receiving general welfare and family benefits and those who qualify for home care, chronic care and extended care programs. In-patients in hospitals and correctional institutions also receive free drugs as do people with specific, designated conditions and diseases. Ontario residents who are not members of these groups must either pay for drugs that have been prescribed for them or purchase private insurance. It is assumed that in this way all residents of Ontario will have access to prescription drugs.

Is this assumption well founded? Do all persons actually get the drugs they need? Alternatively, do some persons get prescriptions for drugs they do not need, or that are not effective and even dangerous for them? These questions, which relate to the mandate of the Inquiry (see section 1.2) reflect the place of prescription drugs in our health care system.

Although all drug treatment involves a degree of risk, when used appropriately pharmaceutical products can protect our health and, at times, our very lives. When used

inappropriately, they can themselves produce illness or even death, as well as contributing to unnecessary expenditure of public funds.

## 2.3 The Appropriate Role of Government

It was repeatedly made clear during the Inquiry's public hearings that Ontarians continue to look to government to ensure access to prescribed drugs of high quality. Neither geographic location within the province nor economic status are regarded as acceptable barriers to obtaining promptly the pharmacotherapy that the public rightly regards as an essential component of health care. At the same time, Ontarians increasingly recognize that the affordability of prescription drugs is a valid concern for all health care payers. In other words, those responsible for managing tax-supported drug benefit plans and private insurance plans must strive for the most cost-effective use of prescription drugs as vigorously as consumers who pay for medications out of pocket.

In the three sections that follow (2.4 to 2.6) the role of government with respect to these objectives is discussed in greater detail.

However, it is important to note that in Ontario, as in Canada generally, there is no clear consensus regarding the limit of the responsibility of our provincial and federal governments with respect to health care, including prescription drugs.

To what extent are health care professionals rather than governments responsible for the quality of the health care received by Canadians? What role do governments legitimately have in regulating dentistry, medicine, nursing and pharmacy which traditionally have been self-governing professions?



What about the public; do consumers share responsibility for maintaining health and for treatment decisions? To what extent should consumers who can afford it contribute to the cost of their treatments?

What is the appropriate role of government in relation to private industry in the health care field? Should pharmaceutical manufacturers and distributors (and other suppliers of necessary health-related products) be subjected to more stringent regulations and be held to higher ethical standards than business generally? In our free market economy is more government control of the health related industry justifiable?

A systematic examination of these issues is clearly beyond the mandate and expertise of this Inquiry. However, in our work we have been well aware that they cannot be ignored and that important decisions related to our mandate have to be made even before a clear public consensus can be reached. Therefore, in formulating our recommendations to the Ontario government, and to government-related and government-funded organizations, we have not held back from taking positions related to these issues. We recognize that some of these positions may be contrary to the existing policies of professional bodies and the government of Ontario. However, these policies are in a state of evolution as our health care system continues to be the object of close scrutiny. We have reason to hope, therefore, that as the recommendations contained in this report are considered on their own merit, deviation from current professional or government policy will not create obstacles to their implementation. Indeed, we hope that they will contribute to the further evolution of public policy related to health care in Ontario and Canada.

## 2.4 Assuring Drug Quality

Prescription drugs are unlike most commercial products. Ordinarily consumers are able to evaluate items for sale in relation to their needs or preferences; no special expertise is required and only a degree of protection by legislation and government regulation is needed. By contrast, prescription drugs (and indeed many drugs that currently do not require a prescription) are powerful chemicals whose value, price, benefits and risks cannot be critically evaluated by most consumers. We therefore depend upon highly trained health care professionals, such as physicians and dentists, to determine when we need such potent chemicals, and rely on pharmacists to dispense them. In that more than 5,000 different pharmaceutical products are currently licensed for sale in Canada, consumers must rely on these professionals to select those drugs that are most likely to benefit them when they become ill.

However, practising health care professionals themselves do not have the resources or the expertise to evaluate the safety, efficacy and cost effectiveness of all pharmaceutical products. They must rely on experts in chemistry, biochemistry, toxicology and pharmacology to provide this information and keep them up to date with respect to changes in this rapidly moving field.

In Canada, as in most countries, the national government has the responsibility of licensing drug products once their safety and efficacy has been established. This task is performed by the Health Protection Branch (HPB) of Health and Welfare Canada, in Ottawa. However, the Ontario MOH subjects drug products to further scrutiny with the advice of the Drug Quality and Therapeutics Committee (DQTC). While the federal HPB confirms that drugs licensed in Canada are safe and can be beneficial in relation to the indications for their use, the Ontario government agencies

have gone further in seeking to assure that those drugs listed in the ODB formulary are worthy of reimbursement. Those drug products considered to be interchangeable because they produce the same effects are identified. (These issues are discussed in detail in chapters 4 and 5).

However, it is possible that the Ontario government does not go far enough. Prescribers are still expected to be familiar with a large number of drug products of variable effectiveness and cost and tax-supported reimbursement under the drug benefit plan still occurs even when the benefit-risk and benefit-cost ratios for some prescribed products are not as favourable as for alternative products available.

The Ontario government has the tools needed for this task. The ministries of Health and Colleges and Universities have budgets which can be applied to promote needed research and educational initiatives in Ontario's five health science centres. These can greatly influence the behaviour of prescribers (physicians and dentists), dispensers (pharmacists) and those who administer drugs (nurses).

The professional colleges can be asked to review regulations that relate to relevant professional standards and practice, the interaction of professionals and the pharmaceutical industry, as well as standards for distributors of drugs. The MOH, in association with the professional associations (such as the Ontario medical, nurses' and pharmacists' associations) can sponsor public education campaigns to promote rational use of both prescription and non-prescription drugs. The MOH can use its legislative authority and regulations to establish more stringent criteria for the listing and reimbursing of drug products.

## 2.5 Assuring Appropriate Access

The appropriate use of prescription drugs is an integral part of high quality medical care. When the foundations of Canada's much admired health care system were laid in the Hall Commission report of 1964, prescription drugs were intended to be included in a comprehensive, publicly supported health care plan. However, as Ontario and the other provinces entered into agreements with the federal government to implement the 1968 Canada Health Act, out-patients' prescription drugs were not included as benefits.

From the point of view of optimal health care this was not a logical decision. It is true that the most severe illnesses are primarily treated in hospitals, where pharmacotherapy is included as a benefit. However, follow-up drug treatment after discharge from hospital, and out-patient drug treatment for people who are ill but do not need hospitalization, can be as important as other interventions—for example, out-patient surgery—that are covered.

Quite properly, Ontario and other provinces have instituted various programs during the past 25 years to extend tax-supported coverage to persons who need out-patient drugs but cannot afford them (see section 3.1). At present almost 20 per cent of Ontarians are covered by the ODB plan and other provincial or federal programs. A further 65 per cent have third-party, private insurance, largely through their employment (see section 5.3). It is often assumed that the remaining 15 per cent of Ontarians have either chosen not to purchase insurance that covers out-patient drug costs, or feel they can afford to pay for these out-of-pocket when they are needed.

Unfortunately, this is not always the case. Persons under 65 who are employed and do not receive public assistance are not eligible for ODB benefits, even when their income is very low. When they have high, unexpected or

chronic drug costs the result can be catastrophic. Some persons with serious long term illnesses or disabilities do not qualify for insurance by the private plans available and others, who have insurance, can quickly exhaust their benefits and also suffer catastrophic costs.

It is the view of the Committee that our federal and provincial governments have an obligation to ensure that the basic values implicit in the Canada Health Act are implemented with respect to appropriate pharmacotherapy as well as other health care services. These values include access to these services, including prescription drugs, by all Canadians who need them. The Committee considers it unacceptable that some Ontarians do not have ready access to necessary pharmacotherapy at a time when prescription drugs are provided under ODB to some Ontarians who could afford to pay for them directly or by purchasing insurance. Certainly other health care services, that are no more important, are universally available.

We believe that the Ontario government has an obligation to rectify this situation, and this is reflected in our recommendations in this regard. As long as public policy under the Canada Health Act involves the provision of universal, comprehensive publicly supported and administered health care services, the ideal would seem to be to cover all necessary out-patient drug costs—as in-patient costs are covered—for the entire population. If this is not affordable, it seems logical that we should at least live up to the spirit of the Canada Health Act by ensuring that all Ontarians who need prescription drugs but cannot afford them are covered, even if it means that some who are already covered but could afford to pay are required to contribute a co-payment for out-patient prescription drugs.

It is important to note that public coverage for out-patient prescription drugs has never been universal in Ontario. Initially a select group of persons over 65—those who received social

assistance—were beneficiaries of the provincial drug program. This changed in 1975 when coverage was extended to all seniors. Most Ontarians under 65 have never been covered. Therefore, to institute a co-payment for out-patient prescriptions, with an exemption for those who cannot afford it, is not a violation of the principle of universality.

## 2.6 Assuring Affordability

Although the Canadian health care system is widely admired, a number of strains in the system have become apparent in recent years. The most important of these relate to affordability. As health care costs rise faster than other components of the cost of living in Canada, and as provincial governments shoulder an increasing proportion of these costs, health care assumes an even larger proportion of provincial budgets, threatening other desirable social programs and the wealth creating programs that make them possible.

The threat to the integrity of our health care system is obvious; the challenge is to address the problem of rising health care costs without undermining the system itself — as has happened in other countries— and without abandoning the principle of universal access to necessary and high quality health care.

Although governments have the principal responsibility of ensuring that public funds are spent wisely others, including health care professionals, managers of health-related industries (such as pharmaceutical manufacturers and distributors) and the public itself share this responsibility. Unless each of these groups is prepared to accept its portion of this shared responsibility, there is grave risk that the excellent health care system, of which Canadians are so proud, will be eroded by an unacceptable reduction in quality or will be so distorted by unwise cutting of entitlements that its basic values will be lost.



With regard to the mandate of this Inquiry, the Committee became convinced that each of the interest groups must contribute to making optimal pharmacotherapy for Ontarians possible. As we indicate elsewhere, optimal pharmacotherapy is affordable, high quality pharmacotherapy.

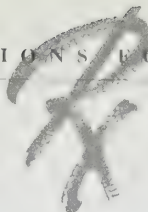
The Ontario government must take the lead in promoting cost-control that protects rather than erodes excellent health care and must use all its influence and authority to achieve this objective. Legislation, licensing policy, regulations, selective funding of programs, use of purchasing power, taxation, and public education are all levers that can be applied by government. We believe that they should be employed judiciously but boldly to protect the essence of our health care system by keeping it affordable.

It is important that the public remains aware of the complexity of this task. What is needed is system-wide planning and carefully designed and evaluated pilot projects rather than ad-hoc decisions and the premature application of untested innovations. Since prescription drugs are only one of the factors that influence health status, policies designed to improve drug quality and reduce cost must be evaluated with regard to their impact on other aspects of health care.

Since governments are always under pressure to respond to unexpected problems that arouse public concern, it is difficult for them to establish long term strategic plans and to adhere to them. The task of government is rendered more difficult when evaluation of the cost-effectiveness of components of the system, such as prescription drugs, is added to the work load.

Nevertheless, we believe that the MOH must accept this challenge to an even greater extent than it does now. But this cannot be done without meaningful ongoing consultation with health care providers, health care-related industry and consumers. A coalition of the interested parties is essential. Adversarial relationships in the health care arena are rarely constructive and, for the most part, are self defeating.

Therefore, it is important that the Ontario government seek consensus on the need for responsible cost-control in the interests of preserving a worthwhile health care system. In this report we make a number of recommendations which, if implemented, should result in a substantial reduction of the cost of government drug programs without a reduction in the quality of pharmacotherapy. Indeed, we believe that their adoption will result in better care. Our recommendations ask each of the major interest groups—health care professionals, manufacturers, the government and the public—to give up something in return for a greater good that will not only contribute to protecting the health care system but will also, in the long run, serve the strategic interests of each group.



## Chapter III

### Prescription Drug Programs in Ontario

*This section briefly describes the evolution of prescription drug programs, including federal and provincial government initiatives to ensure that Canadians and Ontarians have access to quality drugs at reasonable prices (see appendix 3.1, page 32.) Events leading up to the initiation of the Ontario Drug Benefit (ODB) program, its current organization, and an analysis of ODB expenditures are presented. Lastly, this section provides a summary of other provincial drug benefit programs as a basis for comparison.*

#### 3.1 Origin and Growth of Drug Benefit Programs

The impetus for drug benefit programs originated from government concern that residents of Ontario were not receiving necessary medications because of financial barriers. Although access to prescription drugs for those requiring financial assistance has improved over the years, a number of federal and provincial initiatives were intended to influence the quality and cost of medications to Canadians. Despite these efforts and the availability of private insurance plans, the provincial government decided (several years after installing the health insurance program) to address the issue of access once again. It was at this time that the ODB program was initiated.

##### 3.1.1 Access to Prescription Drugs in Ontario

Public funding in Canada for prescribed drugs began in 1957 with the federal Hospital Insurance and Diagnostic Services Act. When the Act became operative on July 1, 1958 only five provinces had entered into agreements with the federal government. By January 1, 1959, Ontario (along with Nova Scotia and

New Brunswick) followed suit. This agreement resulted in a hospital insurance program, the costs of which were to be shared equally by the federal and provincial governments. Under this program, insured medical services in hospital included prescribed drugs.

In 1962, the Ontario government introduced two programs under the General Welfare Act — special assistance and supplementary aid — to provide financial assistance for prescription drugs to general welfare and family benefits recipients. Although funding was to be shared by both the provincial government and the municipalities, eligibility and benefits were determined by individual municipal governments. The resulting uneven program standards across municipalities became a major consideration leading to the establishment of a provincial drug benefit program.

In addition to publicly sponsored hospital programs and special arrangements for persons requiring social assistance, private health insurance policies also assisted with the drug costs for a significant number of individuals. Insurance agencies (such as the Ontario Blue Cross) extended health care plans to cover drug expenditures on a cost-

sharing basis. In 1957, Prescription Services Inc. established the first private prepaid drug plan in Ontario (known as the Green Shield Plan). These plans were generally directed to employees; at present, fewer than 1 per cent of Green Shield's subscribers are covered through policies purchased as individuals.<sup>1</sup>

In 1964, the federal Royal Commission on Health Services chaired by Chief Justice Emmett M. Hall made far-reaching recommendations designed to ensure access for all Canadians to the best possible health care. The Hall Commission recommended that prescribed drugs be included as a benefit of the proposed universal health insurance program. This conclusion was based on the assumption that drug therapy is an important component of health care, and on evidence that for the average Canadian family, the burden of drug expenditures was almost as great as paying physicians' bills. The information available at the time showed expenditures on prescribed and non-prescribed drugs in Canada in 1961 to be \$364 million; expenditures in the same year for physician services were \$583 million.<sup>2</sup> The Hall Commission noted that the "incidence of drug expenditures is to some extent predictable, particularly in average terms for certain age groups (the elderly). On the other hand, it is difficult to foresee the incidence of very heavy drug costs, for serious illnesses that may strike at random."<sup>3</sup>

The Hall Commission concluded that despite hospital prescription drug coverage, assistance to persons on social assistance, and the availability of third party insurers, public concern about drug costs remained high. The Commission therefore endorsed the inclusion of outpatient prescription drugs as a publicly insured benefit and considered some form of

monetary participation by the patient. The experience in other jurisdictions (New Zealand, Australia, Norway, Denmark, the Netherlands, Britain) and in Canada (Saskatchewan), pointed to increased utilization when a public program finances prescription drugs. The Commission recommended a \$1 contributory payment for each prescription with the exception of those individuals on long-term therapy. Such direct patient contribution was viewed as "a means of encouraging responsible use of drugs."<sup>4</sup>

Shortly thereafter, the federal government enacted the Canada Health Act (1968) which established a national health insurance program. However, contrary to the Hall recommendation, prescription drugs were not included as a benefit.

As a result of the exclusion of prescription drugs from the national universal health insurance plan, access to quality prescription drug products, and their cost, continued to be major governmental concerns in Ontario.

### 3.1.2 Quality and Cost of Prescription Drugs in Ontario

As early as 1960, the provincial government had set up a Select Committee of the Legislature to examine the cost of drugs in Ontario. This Committee issued its final report three years later, observing that the "Ontario Department of Health (now the Ministry of Health, or MOH) which purchases the drugs used in its mental institutions and sanatoria is the largest single purchaser of drugs in Ontario."<sup>5</sup> Consequently, the committee believed that the government ought to be able to ensure a high level of quality and reasonable prices for such

<sup>1</sup> Hurley, J. An examination of access to prescription drugs in Ontario and an evaluation of selected cost-sharing policies.

<sup>2</sup> Hall, E.M. (Honorable). *Royal Commission on Health Services*, Vol. II, Toronto, Ontario, p.55.

<sup>3</sup> *Ibid.*, p.555.

<sup>4</sup> *Op. Cit.*, p.365.

<sup>5</sup> Hon. H.L. Rowntree, Q.C. *Report of the Select Committee of the Ontario Legislature*, 1962 p.46.



products. A drug testing laboratory, and use of generic products wherever possible, were major recommendations and the idea of a central government pharmacy was raised.

**3.1.2.1 PARCOST:** In 1968, the government of Ontario introduced the PARCOST (prescription drugs at reasonable cost) program to provide the public and health professionals with information on the quality and price of drugs. Not only did the provincial government initiate testing of generic products through its drug testing laboratory, it also allowed for inspection of the premises of manufacturers of selected drugs. As the report of the 1973 task force which reviewed the PARCOST program stated: "The intention of these efforts was to provide assurance to doctors, pharmacists and other prescribers and purchasers that some less expensive preparations are safe and potent and could be prescribed and dispensed with confidence in their quality."<sup>6</sup>

A major component of the program was the comparative drug index (CDI). Pharmacies participating in PARCOST agreed to dispense and charge the CDI listed price of products, plus a negotiated dispensing fee, on a voluntary basis. Preliminary surveys conducted by the MOH indicated that physicians lacked confidence in the quality of inexpensive drugs at a time when several new pharmaceutical manufacturers were adding to the proliferation of pharmaceutical products on the market. While they were intended to compete with existing products, uncertainty arose due to some treatment failures involving these new products.

To overcome this lack of confidence, the government decided that an independent committee of experts be struck to ensure the quality of Ontario drug products. Since that

time the Drug Quality and Therapeutics Committee (DQTC), which includes specialists in the fields of medicine, pharmacy and pharmacology, has acted as an independent advisory group.

The first CDI, which listed drugs recommended by the DQTC, was published in 1970. It listed comparable pharmaceutical products of assured quality in order of price.

Using a common antidepressant drug as an example, multiple-source products were listed in the following manner:

#### 64 Psychotherapeutic Agents

Product Name	Manufacturer	Cost per Tab
Amitriptyline 50 mg		
Elavil	MSD	12.5 cents
Deprex	M&M	7.7 cents
Levate	ICN	4.4 cents

This first edition of the CDI was judged to be "a quality control manual"<sup>7</sup> because products were not deemed as interchangeable, nor were the pharmacist or physician exempt from liability should a brand other than that prescribed be dispensed. Following recommendations of the Porter report (1971), subsequent CDIs addressed the issue of therapeutic interchangeability, and included the following statement: "The DQTC considers those 'interchangeable drug products' listed under the same non-proprietary name to be therapeutically interchangeable except where indicated otherwise by the words 'not interchangeable'."<sup>8</sup>

Despite efforts to ensure confidence in the concept of interchangeability, the task force which reviewed PARCOST found that this concept continued to meet strong opposition.

<sup>6</sup> Ontario Council of Health, *Review of the Ontario Parcost Program*, Toronto, Ontario, 1973, p.4.

<sup>7</sup> Porter, J. *Report of the Review Committee on Prescription Product Substitution*, Toronto, Ontario, June 1971, p.5.

<sup>8</sup> See PARCOST/CDI, Jan. 1985. This also includes the statement where interchangeable pharmaceutical product(s) means a product containing a drug or drugs in the same amounts of the same active ingredients in the same dosage form as that directed by a prescription.

The report specifically identified advertising and promotional efforts by sales and technical representatives of major drug manufacturers and the Pharmaceutical Manufacturers Association of Canada (PMAC) as the major influences generating this opposition. The thrust of this activity was to “cast doubt on the efficacy of the less expensive products listed in the CDI as interchangeable with the more expensive ones provided.”<sup>9</sup> Nevertheless, the task force reported that it was “satisfied that the Drugs and Therapeutics Branch and its advisory committee are using the best available and modern methods for evaluating drugs admitted to the PARCOST comparative index, and are using admirable and objective judgement in approving or rejecting candidates for listing in the CDI.”<sup>10</sup> Indeed, the report stated that the PARCOST program, by assuring the quality of lower-cost comparable prescription drugs, and promoting their use, saved the Ontario public over \$5 million in 1972.

### 3.1.2.2 Amendments to the Pharmacy Act:

The next significant policy action was taken by the Ontario government in 1972, following recommendations issued in the Porter report. The concept of product selection or interchangeability was embodied in amendments to the Pharmacy Act. The objectives of this piece of legislation were to allow physicians and pharmacists to prescribe and dispense interchangeable products listed in the CDI, to ensure that the consumer is provided quality products at the lowest possible price and to remove the liability from pharmacists and physicians for complying with the legislation. The significance of this piece of legislation was to support the objectives of the CDI since according to J.R. M. Gordon “publishing a list of interchangeable drug products without having legislation allowing selection and

substitution and protection from liability would considerably weaken the program.”<sup>11</sup>

One weakness of the legislation at that time, outlined in the Gordon Commission report, was that while it proved effective for the ODB market, it did not have the intended effect on the non-ODB market. One of the reasons for this weakness was that while there was mandatory product selection for ODB prescriptions, this was not the case for non-ODB prescriptions. Therefore, when a PARCOST pharmacy product-selected a non-ODB prescription, the PARCOST fee applied; if the same pharmacy chose not to product select, then reimbursement was provided for the price of the product set out in the CDI, plus the PARCOST dispensing fee. Pharmacies not participating in PARCOST were under no obligation with respect to dispensing fees and could charge the customer for the price of the product listed in the CDI, plus a usual and customary fee. The discrepancy in fees acted as a disincentive for pharmacies to participate in the voluntary PARCOST program.

At the same time that the province was making major policy decisions about the quality and prices of prescription drugs, the federal government took steps to encourage price competition in the retail drug market. This was achieved through supporting the growth of a generic manufacturing sector by amending the Patent Act in 1969 to allow compulsory licensing to import patented pharmaceutical products.<sup>12</sup> A year later, the federal government commissioned a task force<sup>13</sup> to report on the cost of health services in Canada. Among other issues, the task force examined the assertion that drugs are sometimes prescribed too often and too copiously and concluded that the Canadian Medical Association be requested to formulate guide-

<sup>9</sup> Ontario Council of Health. *Review of the Ontario Parcost Program*, Toronto, Ontario, 1975, p.9.

<sup>10</sup> Ibid., p.15.

<sup>11</sup> Gordon, J.R.M. Report of the Commission on the Pricing of Multiple-Source Drug Products in Ontario, Toronto, Ontario, August 1984, p.43.

<sup>12</sup> Section 41(4) of the Patent Act provides for compulsory licensing to import patented pharmaceutical products. A royalty of 4 per cent of the licensee's selling price of the patented product is levied on firms taking out licenses. In 1983, compulsory licensing in Canada resulted in a savings of \$211 million on prescription drugs sold in Canada. See the report of the Commission on Inquiry on the Pharmaceutical Industry for this information.

<sup>13</sup> National Health and Welfare, *Task Force Report on the Cost of Health Services in Canada: Summary*, Queen's Printer, Ottawa, Ontario, 1970, p.4.

lines for the rational and practical prescribing of drugs; that drugs should be licensed and approved on the basis of effectiveness as well as purity and safety; and that the variety of formulations and sizes of drug products approved for sale be limited to those for which there is demonstrated need. In 1971, the federal government initiated the drug quality assurance program (QUAD) which generated information on drug quality, prices and testing and on manufacturing standards.

Although these initiatives underscored the commitment of both the federal and provincial governments to providing quality drugs to all Canadians at reasonable cost, the fundamental issue of financial access to necessary prescription services was not resolved. For this reason, the provincial government next inaugurated a number of programs to address the gaps in funding for individuals and families with unusually high drug expenditures.

### 3.2 The Introduction of the ODB Program

In 1974 the provincial government took the major step of introducing the ODB program. This program was originally established to provide free drugs to senior citizens eligible for the provincial guaranteed income supplement program for the elderly (GAINS) and to recipients of other government social assistance programs. In 1975, this program was expanded to include all residents of Ontario 65 years of age and over. Eventually, the eligible population receiving benefits from the two municipal programs mentioned earlier (special assistance and supplementary aid) was also transferred to the ODB program.

Eligible benefits were listed in the ODB formulary. The format of listings differed from the PARCOST CDI in that only the lowest price of multiple-source products was provided. This price was the maximum allowable for reimbursement to the pharmacist. If the manufacturer of the product distributed more than 51 per cent of its total line of products through a wholesaler, then the pharmacist would be reimbursed the maximum allowable cost plus 10 per cent for distribution costs. The following is an example taken from the first ODB formulary of September, 1974:

#### 28:16.04 Psychotherapeutic Agents Antidepressants

##### Amitriptyline 50 mg tab

009478	Levate	ICN	0.0440
018341	Deprex	MOM	
016349	Elavil	MSD	

In 1976, the ODB formulary and the CDI (hereafter referred to as the formulary) were combined to serve both the ODB-eligible and the general population. The formulary effectively set a ceiling price for multiple-source drugs; product selection was encouraged by publishing the highest amount that the government would reimburse the pharmacist for the drug product in question (i.e. the published price of the lowest-priced equivalent product available). The role of the DQTC was significant; it included recommending the drugs to be admitted to the formulary, assuring the quality of these products, and determining which drugs were interchangeable (see section 4.2).

Maintaining the economic viability of the ODB program became a challenge by the early 1980s. A number of pressures within the health care system prompted legislation to empower the government to manage and more closely control the drug programs.



Specifically, there were concerns that “price-spreading” was undermining the ODB program and this practice was carefully examined by the Gordon Commission established in 1984.<sup>14</sup>

### 3.2.1 The Price-Spread

As early as 1971, when the Porter Committee submitted its report entitled the “Review of Prescription Product Substitution,” the possibility of price spreading was identified. It worked in the following manner: even though a particular product was listed as the lowest in price, the pharmacist was tempted to dispense the one that was in stock and requested permission to substitute for this brand. There was the tendency to fill prescriptions for generic drugs with higher priced products because some companies were listing prices for smaller package sizes of their brands in the CDI while selling larger quantities to the pharmacy at a cheaper price. With this incentive, the pharmacist was tempted to use the spread in price to advantage by dispensing those products.<sup>15</sup>

The following hypothetical example illustrates price spreading:

	Formulary Listed Price	Pharmacy's Acquisition Cost
Any Drug Brand A	\$10.00	\$9.00
Generic Drug X	8.00	4.20
Generic Drug Y	7.00	4.00

A brand name drug “A” is listed at \$10 together with two generics, X and Y, at \$8 and \$7 respectively. In this hypothetical example, the real price to the pharmacy of the competitive generic drugs X and Y is in the \$4 range. Even though the acquisition cost of Y is

less than X, it is to the pharmacy’s advantage to stock X because the price spread (\$3.80) is greater than for Y (\$3). Since for non-ODB prescriptions involving product selection (that is, the cash market), the pharmacist selects products on the basis of the lowest price *in inventory*; the pharmacy chooses not to stock generic drug Y. While the pharmacy is only reimbursed the lowest price (\$7) for ODB customers, the price spread is still \$2.80 for an ODB sale. Overall, the net profit for the pharmacist is still highest if only brand X is stocked.

“This practice leads to a marketing strategy for generic drug companies competing for a higher listing (as close to the original brand price as possible) to maximize the price spread while continuing to sell at the \$4 market place price. The system encourages a generic manufacturer to avoid being the lowest price drug listed. Thus, the cost of both ODB and non-ODB prescriptions is increasing while the actual acquisition cost to the pharmacy is, in some cases, decreasing.”<sup>16</sup>

The MOH estimated that the difference between the lowest price in the ODB formulary and actual drug costs to the pharmacist was \$14.4 million in 1983. This amounted to some 5 to 6 per cent of total ODB expenditures and represented a major cost to the public.

After two significant reports on the structure of the ODB program, namely the Bailey report and the Gordon Commission report, the province continued to investigate ways to rationalize the program. Two major pieces of legislation were eventually enacted in 1986: the Ontario Drug Benefit Act (the ODB Act, or Bill 54) and the Prescription Drug Cost Regulation Act (the PDCR Act, or Bill 55). Not only do these two Acts reinforce Ontario’s

<sup>14</sup> Gordon, J.R.M. *Report of the Commission on the Pricing of Multiple-source Drug Products in Ontario*, Toronto, Ontario, August 1984.

<sup>15</sup> Porter, J. *Report of the Review Committee on Prescription Product Substitution*, Toronto, Ontario, June, 1971, p.14.

<sup>16</sup> Quoted from a submission to Dean J.R.M. Gordon, Commissioner, *Report of the Commission on the Pricing of Multiple-source Drug Products in Ontario*, Toronto, Ontario, 1984.

commitment to product selection, they also address the government's concerns about growing ODB expenditures.

### 3.2.2 Bills 54 and 55

Bills 54 and 55 were proclaimed and put into force on December 1, 1986. Bill 54 gave the government "the clear legislative authority to manage the Ontario drug benefit program efficiently."<sup>17</sup> Bill 55 was expected to ensure that "all consumers get the information they need to make informed and economical drug purchases."<sup>18</sup> Although a number of the features are derived from recommendations made by Bailey and Gordon, they are nevertheless important to enumerate.

The ODB Act introduced the following changes:

- A negotiated maximum dispensing fee was established with provisions for change dependent upon on-going dialogue with concerned parties. The legislation outlined the negotiating framework for determination of government reimbursed fees.
- The amount of the drug cost to be reimbursed by the government was based on the best available price (BAP) concept plus 10 per cent. The legislation also gave the government discretion at setting BAP; BAP was not restricted to information provided by manufacturers' submissions but could be defined according to drug prices available in Canada. The MOH could also inspect the records of manufacturers, wholesalers and pharmacists to ensure that accurate price data were submitted.
- The requirement of the dispensing limit was extended from 30 to 250 days, thereby encouraging the pharmacist to dispense the quantity prescribed.

The following are features of the PDCR Act which differ from the ODB Act:

- More information is to be provided by the pharmacist to the consumer on the availability of a lower-cost substitute; the prescription receipt must distinguish the cost of the drug and the dispensing fee; and the dispensing fee for interchangeable drugs must be posted.
- The drug cost for interchangeable products is limited to the price (i.e. BAP) listed in the formulary plus 10 per cent "to cover distribution costs and differences in purchasing volume."<sup>19</sup>
- There are no restrictions on setting fees for the non-ODB market (other than those found in professional regulations.)

Both bills enable the government to inspect the records of both manufacturers and pharmacies and also to levy penalties on pharmacists and corporations if any of the regulations are contravened.

These two major pieces of legislation did not get passed without major opposition. Prior to the Acts being passed, the Ontario Pharmacists' Association (OPA) initiated an ad campaign against the proposed bills. The association was particularly concerned with the changes to the dispensing limit, the process for fee negotiations and the regulatory mechanism which allows inspectors to enter pharmacies and seize records to ensure compliance with the legislation. According to Dr. P. Gorecki of the Economic Council of Canada, who has prepared a report for the Inquiry (see appendices, volume II), the fee negotiation process has not made agreement on an appropriate fee any easier; it has made a positive step toward determining the approach to be taken to set the fee. Data analyzed by Gorecki shows that there has

<sup>17</sup> Ontario Ministry of Health News Release, 86/nr-251a, *Drug Legislation Proclaimed Law*, December 1, 1986.

<sup>18</sup> Ibid.

<sup>19</sup> Op. cit.

been little effect from the 'dispense as written' policy; prescriptions continue to be written in relatively small quantities repeated frequently.

The pharmaceutical manufacturing industry viewed the actions taken by the provincial government over the last decade as undesirable government intervention into the marketplace. Submissions by the PMAC and several of its members to the Inquiry attest to this. For example, the brand name pharmaceutical manufacturers view the formulary submission process performed by the DQTC as an unnecessary duplication of the function served by the Health Protection Branch in Ottawa;<sup>20</sup> they also believe that by merging the CDI and the ODB formulary, the provincial government, in effect, controls a major proportion of the Ontario drug market. One consequence of this is that being listed in the ODB formulary became a marketing objective for many manufacturers.

In contrast, we reported in our second quarterly report that *not being listed* in the ODB formulary may have been a 'loophole' which permitted manufacturers to avoid generic competition.<sup>21</sup> This concerned the growth in special authorizations; by becoming eligible for reimbursement as a special authorization under Section 8(1) of the ODB Act, the manufacturer avoided the conditions of interchangeability for the purposes of reimbursement.

Considerable debate continues as to the merits of the legislation and there is concern over using BAP as a price setting mechanism. The innovative pharmaceutical industry regards this system as favouring generic companies.<sup>22</sup> The OPA, on the other hand, is in agreement with the BAP plus 10 per cent

concept, but prefers that BAP be based on realistic package sizes.<sup>23</sup> The OPA would also like to see a more dynamic formulary which would encourage more realistic prices.

Section 18 (2), (3), & (4) of the ODB Act 1986 specifically addresses the issues of BAP and the 10 - 20 per cent upcharge. Prior to this legislation, there was an allowance for wholesale distribution costs by adding 10 per cent to the base price listed in the formulary. The Inquiry has been made aware that the modification in the application of the 10 per cent has had a detrimental effect on pharmaceutical drug wholesalers.

The Canadian Wholesale Drug Manufacturers Association stated in its submission to the Inquiry that: "The 10 per cent pharmacy purchasing advantage negotiated by the Ontario Pharmacists' Association and provided in the new legislation has nothing to do with the traditional distribution cost allowance (10 per cent). The former is applicable at the retail level for whatever purpose the Ministry had in mind. The latter was previously allowed by the Ministry as an addition to the base price in the formulary, which, in effect, is the price of the product at point of use. Today the pharmacist takes the 10 per cent purchasing advantage as being totally his.

"The Ontario government has agreed to pay the cost of distribution for products sold direct because this cost is already built into the direct manufacturer's (i.e. the manufacturer that sells directly to the retailer) price. However, our Ministry of Health, does not recognize this same charge if delivery of the goods is handled by a wholesaler/distributor."<sup>24</sup>

<sup>20</sup> Brief by Rhone-Poulenc Pharma Inc. #24-5200.

<sup>21</sup> Pharmaceutical Inquiry of Ontario, Second Quarterly Report, August 1988, p.8.

<sup>22</sup> Op cit. Rhone-Poulenc Pharma Inc. #24-5200.

<sup>23</sup> Brief by Ontario Pharmacists' Association. #45-5100.

<sup>24</sup> Canadian Wholesale Drug Manufacturers Association, Submission #2-5100 pp. 4-5.



### 3.3 Current Situation

Currently, the payors for prescribed drugs in Ontario consist of the provincial government, private insurance companies and consumers. The federal government provides prescription drug coverage to status Indians and Inuits, war veterans<sup>25</sup>, Canadian Forces personnel, the RCMP and inmates of federal jails.

Prescribed drugs are a benefit while in-hospital, and the provincial government supplies drugs free of charge to eligible beneficiaries. Although the largest program is ODB, the MOH also funds additional programs for drugs, nutrients and assistive devices. There are also a significant number of private insurance plans with varying drug coverage and customer cost-sharing. These plans are usually provided as part of employment benefits. Best estimates indicate that 15 per cent of the Ontario population does not have some form of prescription drug insurance coverage.

#### 3.3.1 Current MOH Drug Programs

The role of the government in the prescription drug market has grown significantly over the past several decades. As table 3.1 shows, government expenditures on prescription drugs are estimated to be almost 50 per cent of total sales of prescription drugs in Ontario.

**Table 3.1**

#### **1988 Expenditure and Sales Estimates For Ontario: Prescription Drugs**

Estimated sales of prescription drugs in Ontario	\$1.2 billion
ODB expenditures on drugs	\$360 million
Public hospital expenditures on drugs	\$230 million

Drug programs are listed in table 3.2.

Apart from the ODB program (which will be described in greater detail below), the MOH also provides drugs and over-the-counter products through the Ontario Government Pharmacy Medical Supplies and Services (OGPMSS). The OGPMSS, or government pharmacy, is a centralized purchasing and distribution function of the MOH which distributes to provincial psychiatric hospitals, correctional institutions and facilities for the developmentally handicapped. A more in-depth analysis of this aspect of the acquisition of drugs by the province is provided in chapter 6.

The MOH funds clinics for confidential treatment and counselling of sexually transmitted diseases (STDs). Drugs used by these clinics for the treatment of STDs are provided free of charge through government pharmacy. Funding is also provided for drugs prescribed by a private physician to a patient for treatment of STDs. The cost of these drugs is usually reimbursed by the municipalities.

Since 1982, the responsibility for treatment of tuberculosis rests with the family physician rather than through clinics. Physicians treating patients and their contacts usually obtain the drugs through local health units, which in turn request them from government pharmacy.

MOH also funds drugs provided through public health units for the treatment of leprosy as well as specific drug products for use in ambulance services under two programs called "basic life support" and "advanced life support." The assistive devices program offers financial assistance for devices with 25 per cent cost-sharing by the patient.

<sup>25</sup> Pensioners and recipients of certain allowances and benefits.

**Table 3.2**  
**List of MOH Funded Programs for Drugs, Nutrients and Assistive Devices**

Program Name	Source of Payment	Means of Funding	Benefits	Est. Popn.	Est. Cost Per Patient	Legislative Authority	Comments
Priority Drug Benefit Program GAINS e Care e Spec  nd Care nic Care t Rehab Hypoglyc Welfare ly Benefits	ODB Kingston	MOH-ODB	Drugs listed in ODB/CDI Formulary	1,492,940	\$370./year	ODB Act/ PDRC Act	*Currently being phased out
Authorizations er ODB Act	ODB Kingston	MOH-ODB	Oxygen, Allergens Inter. non-form benef "limited use" prod Nutrit Supplements Moisturizers, vehicles, bases	n/a	n/a	ODB Act Sect. 8	
Priority Govt. m Med lies & ces (PMSS) h Hospitals** Soc Facilit ect Facilit	OGPMSS invoices each institution	MOH Supply & Services	Drugs & Medical Supplies listed in OGPMSS catalog	100,000*		MOH Policy	*Includes some ODB recipients
es for Aged ng Homes Homes		MOH-ODB	ODB Approved - Non Prescription Drugs				**Includes out- patient medication programs
Program	OGPMSS invoices Public Health Branch	MOH Supply & Services	Drugs related to treatment of STD	29,317/annual (based on attendance at 43 clinics)	\$70,578* (total drug cost for program-'88)	Health Protect & Promotion Act 1983	*Individual costs vary according to number of treatments
rogram	OGPMSS invoices Public Health Branch	" "	Drugs related to treatment of TB	630 patients notified/year			Individual physicians place orders through branch
osy ram	OGPMSS invoices Public Health Branch	" "	Drugs related to treatment of Leprosy				
ulance Serv  Life ort ram	BLS program	Directly funded by MOH	Specific drug products* (IV solution, saline, oxygen)				*Program administered by 5 services/some drugs ordered through OGPMSS
anced Support ram	ALS program	MOH funds base hospitals for supplies	Specific drug products				Physician at base hos- pital delegates respon- sibility for drugs to ALS trained personnel
Assistive Devices ram			75% of cost of -hearing aids -respiratory aids -communicative aids -visual aids -wheelchairs/mobility devices -ostomy supplies -incontinence supplies -prosthetic devices -orthotics				

**Table 3.2**  
**List of MOH Funded Programs for Drugs, Nutrients and Assistive Devices (page 2)**

Program Name	Source of Payment	Means of Funding	Benefits	Est. Popn.	Est.Cost Per Patient	Legislative Authority	Comments
<b>Hospital Based Out-Patient Programs</b>							
<b>End Stage Renal Disease</b> -home dialysis	Global Budget Life Support	Global Budget Life Support	Drugs, Medical & Surgical Supplies	125	\$20,000/year equipment \$20,000	Health Insurance Act Regulation 93	
-cyclosporine	Life Support	Life Support to 9 transplant centres	Cyclosporine	2,400	\$5,000/year	Public Hospital Act Regulation 863	
<b>Hyperalimentation</b>	Global Budget Life Support		Nutrients,equipment, Supplies and related drugs		TPN \$60-\$70/day Equipment \$600/person	Health Insurance Act Regulation 93	
<b>Hemophilia</b>	Red Cross Hospital Budget	MOH funds Red Cross	Blood products, Syringes & equipment	757			
<b>Cancer</b>	-3rd party -Cash -Special Drug Service	MOH funds OCTRF clinics	Chemotherapy drugs		Varies/some are very costly	The Cancer Act Section 10	
<b>Cystic Fibrosis</b>	Invoiced	MOH funds out-patients through 9 existing CF clinics	Antibiotics Enzymes Bronchodilators Vitamins Solutions	860	\$2,500/year (average)		Eligibility expanded as per Lowy recommendation
<b>Thalassemia</b>	Invoiced	MOH funds out-patients through 3 hospitals	Desferal, needles, Syringes Distilled water, Batteries, Pumps, vitamin C	125	\$25,000/year		Eligibility expanded as per Lowy recommendation
<b>In-born Errors of Metabolism</b>	Public Health Branch provides funds to 5 treatment centres and the National Food Centre		-Total cost of special diets -Travel expenses to clinic	4-6/year or 1/25,000 births	Avg. \$3,000/year \$7-\$12/day	None	
<b>AIDS</b>	MOH invoiced	MOH funds thru Sunnybrook Medical Centre	AZT, Pentamidine (aerosolized)	1,300	\$10,000/year \$300/year	Public Hospital Act Amendment to PHA & Health Insurance Act	
<b>Human Growth Hormone</b>	MOH invoiced		Growth hormone	175	\$15,000/year	Public Hospital Act; Health Insurance Act	

Source: MOH document (Current Funding of Out-Patient Drugs & Nutrients)  
 Communication with individual programs or branches, 1989.



A significant number of hospital-based outpatient programs exist for the provision of drugs and other medically related products. Although some products (for example cyclosporin, products used for home dialysis, hyperalimentation and haemophilia) are funded through hospital global budgets or life support programs, the MOH has programs where the hospital invoices for product costs only (e.g. AIDS, cystic fibrosis, thalassemia and human growth hormone programs.)

In its second quarterly report, the Inquiry recommended that eligibility for drug coverage be extended to all persons in Ontario with cystic fibrosis and thalassemia. The MOH acted immediately to implement this recommendation. Previously, only patients under 18 years of age were covered under the program.

**3.3.1.1 ODB Program:** In its presentation<sup>26</sup> before the Inquiry, the MOH identified the mandate of the ODB program as: "assuring the interchangeability of drug products; the provision of quality drugs to all Ontarians at reasonable cost; and the need to consider the impacts of our drug programs on health status outcomes." This is discussed in detail in section 4.1.

For 1988-89, the drug programs branch budget amounted to less than 1 per cent of total ODB expenditures. Almost half of this is devoted to the administration of claims activity (43 per cent); more than a third is for general administration, policy and planning (35 per cent). The remainder is taken up by scientific activities (22 per cent).<sup>27</sup>

Eligible beneficiaries of the ODB program include: all senior citizens 65 years and older, all eligible recipients of family benefits, general welfare assistance, extended health

care benefits, home care benefits, and residents of homes for special care. Participants in the program are eligible to receive prescribed drugs free of charge and benefits are established by the ODB formulary.

The Ontario Ministry of Treasury and Economics stated in *Economic Outlook and Fiscal Review: Ontario 1988* that the ODB plan has experienced an average annual increase of 20.4 per cent. These annual increases have made ODB "one of the fastest growing health care programs over the period [1978-1988]." In its subsequent report, the Ministry points to the declining federal share for health care as adding further pressure to the provincial budget.

In 1977, the established programs financing system was adopted to replace previous federal-provincial cost-sharing programs for health and post-secondary education. This new arrangement of block funding provided greater latitude for the provinces to manage their respective health care and post-secondary educational budgets. However, this arrangement also put an end to the unrestricted federal matching of contributions with provincial expenditures; federal contributions to provincial health care were capped at 1975-76 costs with provisions for annual increases based on a percentage of provincial GNP growth. In 1982, the revenue guarantee compensation was removed.<sup>28</sup> The result is that "federal support for Ontario health and post-secondary education programs has fallen from a peak of 52 per cent of provincial-local spending for these purposes in 1979-80 to under 38 per cent in 1989-90."<sup>29</sup> The current (1990) federal budget has now frozen the amount of the transfer payment for two years.

<sup>26</sup> Brief #36-3400, Oct. 17/88.

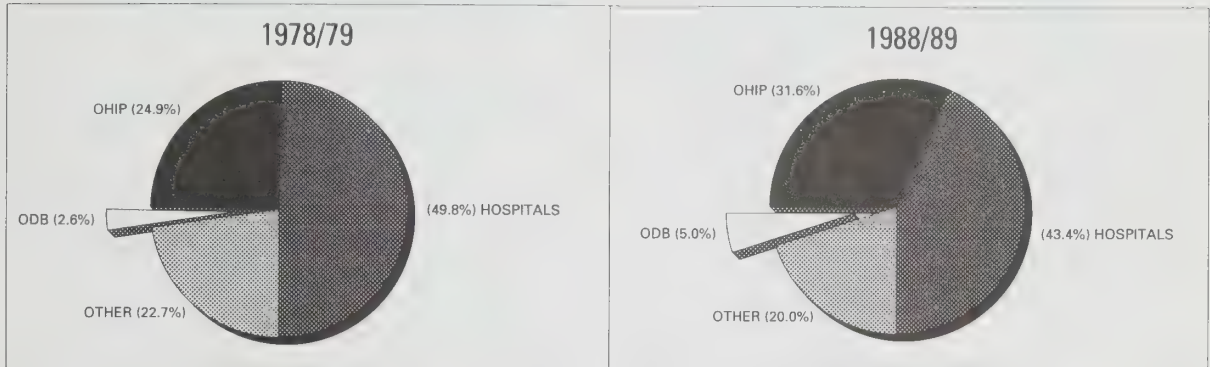
<sup>27</sup> Information taken from "Presentation to the Pharmaceutical Inquiry of Ontario on the Ontario Drug Benefit Program," May 5, 1989.

<sup>28</sup> Ministry of Treasury and Economics, *Economic Outlook and Fiscal Review: Ontario 1989*, Nov. 1989, p.85.

<sup>29</sup> Ibid., p.68.

### 3.3.1.2 Expenditure Profile of the ODB Program

**Components of Health Care Spending: Ontario: 1978/79 vs. 1988/89**



Source: Ministry of Treasury and Economics  
Figure 3.1

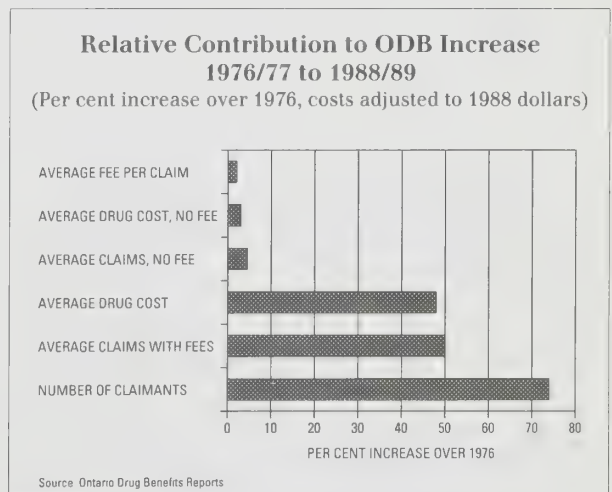
In 1978-79, the ODB program represented only 2 per cent of total health care spending; 10 years later, the program has increased to 5 per cent of the share of health care expenditures in Ontario (see figure 3.1). The increase over the 10 years is 508 per cent or approximately 20.4 per cent annually.<sup>30</sup>

The total paid for the ODB program was \$637.9 million in 1988-89. These expenditures break down as follows:

	\$Millions
<b>Fees Paid</b>	<b>\$197</b>
<b>Drug Cost</b>	<b>\$441</b>
Claims w/fee	\$328.2
Special authorizations	\$62.0
Claims w/o fee	\$50.8
<b>Total Paid</b>	<b>\$637.9</b>

Comparing the distribution of ODB costs for the years 1978/79 and 1988/89 (figure 3.2), the increase has been greatest for claims with

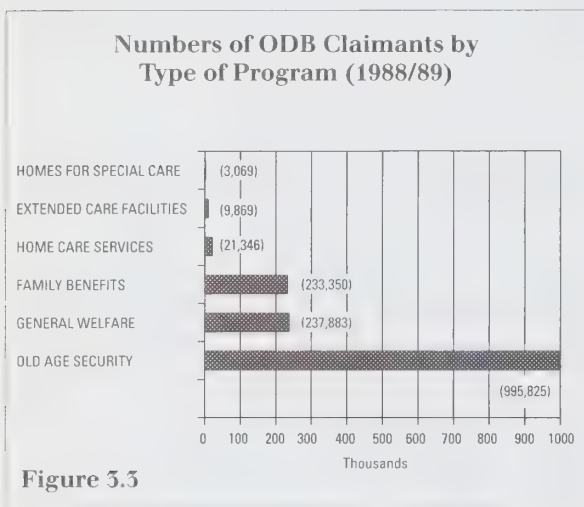
fees. Fees are broken out separately and the figure shows that they now take a smaller proportion of ODB expenditures. This leads to the conclusion that the prescription drug component of the ODB expenditure requires further analysis to explain the increase; this analysis can be found in section 9.1.



**Figure 3.2**

<sup>30</sup> See Economic Outlook and Fiscal Review, Min. of Treasury and Economics.

The Inquiry examined ODB utilization data for the period 1976 to 1988 and found that a number of factors were contributing to the significant increases in expenditures. As shown in figure 3.3, the major contributing factor is the increase in the number of claimants. This factor accounted for 74.3 per cent of the total increase in expenditures since 1976. Figure 3.3 indicates that the number of claimants over 65 years of age accounts for the greatest increase in claimants over the 12 year period. Claims through the Ministry of Community and Social Services represent roughly 20 per cent of ODB expenditures.



The next significant factor influencing the rising ODB expenditures is the average cost of claims with fee. This has had a 50.1 per cent impact on the increases to date. As noted earlier, the major influence on this increase was the average drug cost of the claims which was 48.4 per cent, while the average fee per claim was only 1.2 per cent.

However, the driving force behind the increase in the average cost of claims with fees is not known. While it is evident that cost of drugs is a major component, the data do not

allow us to determine whether the actual cost of drugs has increased substantially, or whether utilization has intensified.

Further analysis of drug prices will be provided in chapter 5.

### 3.3.2 Private Drug Insurance Plans

The two private insurance companies with major drug insurance plans in Ontario are Green Shield Prepaid Services Inc. and Blue Cross. By extrapolation, private insurance companies in Ontario provide coverage to roughly 60 per cent of the population (with approximately 15-20 per cent covered by ODB and 15-18 per cent paying cash.)

As part of his report prepared for the Inquiry, Prof. J. Hurley of McMaster University investigated the impact of third party payors on access to prescription drugs in Ontario. Although considerable data were provided by both Green Shield and Blue Cross, Hurley found that the data did not provide significantly new information which would substantiate or refute the previously estimated percentage of the Ontario population that has some form of drug benefit coverage. This estimate stands at 85 per cent. In his report, he did identify a number of groups that may be facing financial difficulty in obtaining prescription drugs, namely: "Individuals with extraordinary drug expenses, those requiring special drugs, those only employed part-time, and other subgroups who do not qualify for the ODB program or for private third party coverage."<sup>31</sup>

<sup>31</sup> Hurley, J. "An Examination of access to prescription drugs in Ontario and an evaluation of selected cost-sharing policies," Report to the Pharmaceutical Inquiry of Ontario, Oct. 13, 1989.



### 3.3.3 Ministry of Community and Social Services

Many of the presentations and submissions to this Inquiry addressed problems of access to financial assistance for Ontarians experiencing catastrophic drug costs. Several individuals and organizations came forward<sup>32</sup> and expressed specific concerns regarding financial access to prescription drugs. The Social Assistance Review Committee (SARC, 1988) also touched upon the burden of expensive drug regimes on the poor and the “working poor.” For this reason, the Inquiry commissioned a research study to determine the current status of access to prescription drugs by Ontarians. In his report entitled “An examination of access to prescription drugs in Ontario and an evaluation of selected cost-sharing policies,” Prof. Hurley reinforced the problems of financial access that were brought forward to SARC and the Inquiry. A number of options which would ensure accessibility to required medication and maintain the viability of the drug program in Ontario were provided by Prof. Hurley. (See volume II)

Information about the role of the Ontario Ministry of Community and Social Services was provided in that body’s submission to the Inquiry.<sup>33</sup> There are two social assistance programs operating in Ontario: general welfare assistance (GWA) and family benefits assistance (FBA). GWA provides immediate financial assistance for temporary hardship due to illness, unemployment or some other misfortune. This program is delivered by municipalities and Indian bands and funding is the joint responsibility of the federal, provincial and municipal governments. FBA is

a provincial program covering the elderly, the disabled, blind, permanently unemployable and sole support parents.

In addition to providing drug benefit cards to eligible GWA and FBA recipients, the two special programs directed specifically toward prescription drug costs that were mentioned earlier continue to exist. Although these two programs are directed toward GWA and FBA recipients who are already eligible to receive prescribed drugs free of charge, they also provide assistance for products not covered in the formulary. Assistance is also provided to the “working poor” and recipients of other government social assistance programs who may not be eligible for the ODB program (e.g. those under 65 years of age receiving CPP benefits). Benefits offered by the special assistance program are shared equally between the province and the municipal governments, while the supplementary aid program requires the municipal government to contribute 20 per cent of the cost.

### 3.4 Other Provincial Prescription Drug Plans

Each of Canada’s 10 provinces and two territories have publicly-funded programs. Although the primary goal of each program is similar—viz. to ensure that there are no financial barriers which may limit access to necessary medication—the approach to achieving this goal is quite different in each jurisdiction. What follows is a brief comparison of the salient features of the drug benefit programs in Canada. For a detailed report and analysis refer to Prof. J. Hurley’s report, in volume II.

<sup>32</sup> Briefs from: Angela Ombriccolo (13-3500), Cystic Fibrosis Foundation (15-3300), Mary Cascagnette (19-3500), Dr. G.K. Martin (20-3700), Helen Jutzi (22-3500), Cystic Fibrosis Foundation, Cornwall chapter (23-3300), Ontario Nurses Association (35-3100), Rho Pi Phi International (44-3200), East End Health Centre (45-3700), Income Maintenance for the Handicapped Coord. Group (46-3300), Ontario Coalition for Senior Citizen’s Organizations (76-3100), Ernie Epp (99-3400), Helen Gormley (105-3500), College of Nurses of Ontario (107-3700), OMA (115-3100), Kiwanas Club of Ottawa (116-3100), Advocacy Resource Centre for the Handicapped (130-3300), PUSH Ontario (131-3300), Manitoulin-Sudbury DHC (134-3400), Dennis McLay (136-3500), Cystic Fibrosis Foundation, Thunder Bay chapter (139-3300), Brian and Marie McGuire (151-3500), A. Thompson-Guppy (152-3500), Kidney Foundation of Canada (153-3300), City of Toronto, Department of Public Health (166-3100), Metro Toronto Epilepsy Association (169-3100).

<sup>33</sup> Brief #109-3400, November 1988.

### 3.4.1 Eligibility

Four provinces (British Columbia, Alberta, Saskatchewan and Manitoba) have universal programs that essentially allow eligibility to all residents. The Newfoundland and Labrador program allows access to only seniors and social assistance recipients. The remaining provinces and territories (Ontario, New Brunswick, Nova Scotia, P.E.I., Quebec, Yukon and Northwest Territories) are targeted to benefit seniors, social assistance recipients and at least one other group.

### 3.4.2 Beneficiary Cost-sharing

While a number of provinces do not require financial participation by the recipient, there are provinces which have introduced different forms of beneficiary cost-sharing commonly referred to as “co-payments” (Alberta, B.C., Manitoba, N.B., P.E.I. and Saskatchewan.) The co-payment mechanisms can involve some combination of deductibles, a coinsurance rate, a per-prescription charge, or a cap on expenditures. Only Ontario, Nova Scotia, the Northwest Territories and the Yukon require no cost-sharing.

### 3.4.3 Benefits

The range of benefits is another factor which distinguishes each provincial program. Eligible benefits are defined by a formulary listing or a schedule in Ontario, Newfoundland, Saskatchewan, Quebec and the Northwest Territories. The remaining provinces/territories (Manitoba, the Yukon, B.C., Alberta, New Brunswick, Nova Scotia and P.E.I.) do not have formularies or schedules. Therefore, eligible benefits are all drugs for which a prescription is required by law.

### 3.4.4 Product Selection

This is another feature of provincial drug programs. Only two provinces, Saskatchewan and Newfoundland, currently legislate mandatory product selection. In these two provinces, a pharmacist is required to dispense the lowest-priced interchangeable drug listed in the formulary or schedule unless the physician marks “no-substitution” on the prescription. A permissive type of product selection is practiced in Ontario, Alberta, B.C., New Brunswick, Nova Scotia, Quebec and Manitoba. Permissive implies that the pharmacist is allowed, but not required, to dispense a lower-cost interchangeable.

### 3.4.5 Administration

There are also administrative differences in determining drug cost and other components such as dispensing fees and dispensing limits. Ontario is the only province which defines drug cost as the best available price (BAP) plus a mark-up. The manufacturer’s suggested price, or simply the price listed in the formulary, is the most common definition of drug cost. Actual acquisition cost (AAC) is the third method for defining drug cost and is defined as the net cost to the pharmacy after discounts, rebates, etc. have been applied. Currently, B.C., Nova Scotia, Manitoba and P.E.I. use this definition.

Table 3.3 provides a summary of the eligible groups, the type of “co-payment” arrangement and the dispensing/professional fee for the provinces and territories.

### 3.4.6 Current and Future Trends

Over the last few years, several of the provinces have commissioned studies to examine their health care programs and expenditures.<sup>34</sup> A common feature of these reports has been the concern over rising drug benefit expenditures. Within this context, recommendations regarding the drug benefit component have been made in each report. While the recommendations address changes or modifications to specific features of each province's program, the underlying objective is to emphasize improved quality of care. Cost containment is regarded as a secondary outcome.

Over the years, each province has introduced different mechanisms to assist it in controlling the expenditures of the drug benefit component of health care programming. The various commissions, studies and reports are expected to have an influence on current and future health care delivery and ultimately on the funding of prescription drugs. Therefore, even as this report is being written, changes may be taking place in other provinces. A brief description of a few provincial programs concludes this section.

**3.4.6.1 Nova Scotia:** *The Report of the Nova Scotia Royal Commission on Health Care: Towards a New Strategy* states that the cost to run the Pharmacare program has been increasing 18 to 20 per cent annually over the last 10 years. When it was first initiated in 1975, the total cost of the program that year was approximately \$7 million. In 1989-90, the cost has risen to \$76 million. Roughly 15 per cent of Nova Scotia's residents (seniors and those on social assistance) are covered by Pharmacare.

Until the release of the Royal Commission's report, Nova Scotia had established limited cost control measures for the Pharmacare

program. An incentive payment of \$0.50 is added to the dispensing fee for each prescription that is product selected. However, one important difference between this program and the Ontario Drug Benefit program is that there is no protection from product selection liability.

**3.4.6.2 New Brunswick:** New Brunswick has two programs which provide government assistance for prescription drugs: the Health Services Pharmaceutical program and the Prescription Drug program. The former was established in 1971 and includes benefits to recipients of social assistance and their dependents, recipients of child welfare and some mental health patients. The latter program, established four years later, provides benefits to a wider range of individuals.

In 1988, the government of New Brunswick established a commission to look into the province's health care system and to seek recommendations that could lead the system to "function in the most efficient and cost effective manner."<sup>35</sup> The report notes that expenditures under the Prescription Drug program have increased at an average annual rate of 11.4 per cent for the period from 1984-85 to 1988-89. The annual rate of increase for the Health Services program is greater, at 15.4 per cent annually, over the same period. New Brunswick's two programs represent about 16.6 per cent of the total provincial population and, as in Ontario, the two programs represent 5 per cent of total provincial health care expenditures.

In May of 1988, New Brunswick introduced changes to its program. The two important changes were: seniors not receiving financial assistance became responsible for paying the full cost of the drug dispensing fees; and the dispensing fee ceiling was raised from \$45 to \$120 for seniors receiving social assistance.

<sup>34</sup> *The Nova Scotia Royal Commission on Health Care*, Nova Scotia Government, Halifax, N.S., December, 1989; *Report of the Commission on Selected Health Care Programs*, New Brunswick Government, Fredericton, N.B., July, 1989; *Report of the Study into the Growth in Use of Health Services*, Saskatchewan Health, Regina, Saskatchewan, January, 1989.

<sup>35</sup> Report of the Commission on Selected Health Care Programs, New Brunswick, July 1989, p.1.



Table 3.3

# Condensed Summary of Provincial and Territorial Drug Reimbursement Programs

Province/ Territory	Program Category	Beneficiary Copayment	Basic Professional Fee Dispensing Fee	Expiry Date
Alberta	65+ Miscellaneous Social Assistance	20% of Rx 20% of Rx + balance of premium None	\$6.30	30/06/89
British Columbia	65+  Long-term care Social Assistance Universal(< 65)	75% of fee up to \$125 max.  None None \$325/family + 20%(\$2000. max)	\$5.94	(Average fee for Feb./89)
Manitoba	65+ Long-term care Social Assistance Universal(<65)	\$88.50/family + 20% thereafter None None \$156.15/family + 20% thereafter	\$6.50	31/03/90
New Brunswick	65+ & home care Disease related Long term care Miscellaneous  Social Assistance	\$6.34/Rx (GIS: \$120 max.) None None "Special" cases: same as for 65+ Extra-mural hospital: none Ranges from none to \$2/Rx	1. \$6.30 2. \$6.45	1. 30/06/89 2. 30/06/90
Newfoundland	65+ (with GIS) Social Assistance	Dispensing fee None	65+: \$6.40 SA: \$5.90	65+: Average for Mar.89 SA: 31/03/89
North West Territories	60+ Disease related Social assistance	None None None	\$7.85	30/06/89
Nova Scotia	65+ Disease related Social assistance	None None None	\$7.53	30/06/89
Ontario	65+ Home care Long-term care Social assistance	None None None None	\$6.22	30/11/89
Prince Edward Island	65+ Disease related Social assistance	Fee=1st \$4 of ingredient cost None None	65+: \$6.35 Insulin: 25% markup SA: \$6.60 (no fee at gov't dispensary)	65+: 31/12/89 SA: 31/10/89
Quebec	65+ Social assistance	None None	\$4.70 (1st 20,000 Rx) \$4.05 thereafter)	31/05/89
Saskatchewan	65+  Disease related Long-term care  Miscellaneous  Social assistance Universal (<65)	\$75/family + 20% thereafter \$50/single senior + 20% None. Diabetic supplies: nominal charge Palliative care: none Nursing homes: Maximum of \$3.95/Rx "Unique circumstances": 20% of Rx Provincial wards and inmates: none Ranges from none to \$2/Rx maximum \$125/family + 20% thereafter	1. \$6.00 2. \$6.25 3. \$6.50	1. 30/09/89 2. 30/09/90 3. 30/09/91
Yukon Territory	65+ Disease related	None None	\$7.50	30/04/89

GIS = guarantee income supplement

Rx = prescription

SA = social assistance

Source: Bureau of Pharmaceutical Surveillance, Health Protection Branch, Health and Welfare Canada, May, 1989

**3.4.6.3 British Columbia:** In British Columbia, the total cost of the Pharmacare program has increased 40 per cent over the two years 1985 to 1987. As a result, the government made two significant changes to the program. First, the drug cost was determined by the actual acquisition cost (AAC) and second, seniors were required to pay a 75 per cent co-payment on dispensing fees. One major criticism of the second change to the program is that while many health care organizations are advocating the use of one pharmacy, the co-payment on dispensing fees actually encourages "shopping around" for lower dispensing fees, thereby lowering the cash outlay by the senior.

**3.4.6.4 Saskatchewan:** In 1989, a report entitled *A Study into the Growth in Use of Health Services* was published. The study reports that expenditures per person for drug material costs went from \$15.72 in 1977-78 to \$58.69 in 1985-86. This reflects an increase of 273.3 per cent or an annual increase of 17.9 per cent. Surprisingly, the study reveals that while price increases represented 29.6 per cent of overall increases, the increased volume per person represented 43.4 per cent. Of the 43.4 per cent, only 3.3 per cent was attributed to an ageing population.

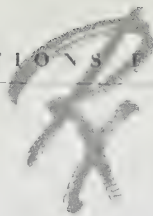
Saskatchewan, as Alberta, initiated a triplicate prescription program in August 1988. The program is run by the College of Physicians, the College of Dental Surgeons of Saskatchewan and the Saskatchewan Pharmaceutical Association. More recently, however, the health ministry introduced a deductible and Saskatchewan is the first province to introduce a "smart card." This is a card which utilizes a magnetic strip to facilitate collection of data for a potential drug utilization review, to verify eligibility, assist in billing and claims payment and to allow pharmacists access to a more comprehensive patient data base.

## Appendix 3.1

### Federal and Provincial Initiatives in the Prescription Drug Marketplace

Federal	Year	Provincial
PMPRB Price Guidelines (Implemented)	1989	ODB-Special Authorizations discontinued
PMPRB Price Guidelines (Published)	1988	MOH extends eligibility for cystic fibrosis and thalassemia patients
Bill C-22	1987	-Lowy Inquiry
	1986	Ontario Drug Benefit Act/Prescription Drug Cost Regulation Act (Bills 54/55)
Eastman Commission (Inquiry into the Pharmaceutical Industry)	1984	Gordon Commission (Pricing of Multiple-Source Drug Products in Ontario)
	1978	Bailey Committee (Report of the ODB Formulary Pricing Committee)
	1977	CDI/Drug Benefit Formulary combined
	1975	Extension of ODB to <i>all</i> senior citizens in Ontario
	1974	Ontario Drug Benefit Program (ODB) established
	1972	Amendments to Pharmacy Act (product selection/removal of liability)
Drug Quality and Assurance Program (QUAD)	1971	Porter Committee (Review on Prescription Product Substitution)
Task Force Report on the Cost of Health Services in Canada	1970	First Comparative Drug Index (CDI)
Bill C-102, Amendments to Patent Act	1969	
Canada Health Act	1968	Introduction of PARCOST and formation of DQTC
Royal Commission on Health Services (Hall Report)	1964	
	1962	Special Assistance/Supplementary Aid (General Welfare Act)
	1960	Select Committee of the Legislature: Examination into the cost of drugs in Ontario
	1959	Ontario enters into agreement with federal government re: hospital insurance program
Hospital Ins. & Diagnostic Services Act	1957	





## Chapter IV

### The Formulary and the DQTC

*This chapter contains a discussion of, and recommendations relating to, the Ontario Drug Benefit formulary, the Drug Quality and Therapeutics Committee, special authorizations and generic drug product substitution.*

#### 4.1 Drug Quality & Therapeutics Committee (DQTC)

Both the Ontario Drug Benefit (ODB) formulary and the Drug Quality and Therapeutics Committee (DQTC) form an integral part of the ODB plan's evolution.

As indicated in greater detail in section 3.1, the late 1950s and early 1960s were marked by a growing interest in reimbursement plans for prescription drugs, largely because of the significant cost of pharmacotherapy.

One of the programs which was established both to improve the quality and reduce the cost of reimbursement, was the Prescription Drugs at Reasonable Cost (PARCOST) program, which was preceded by the establishment of the DQTC. At its inception, the initial DQTC, comprising seven members, was given the mandate to ensure that reliable drugs of quality were available to hospitals and the public.

The committee appears to have received its mandate as a result of concern about the uncertain quality of new drugs at a time when the pharmaceutical industry was burgeoning with new manufacturers and a proliferation of new products, some of which were being marketed in competition with existing products. Some of this uncertainty arose from

reported failures in treatment using new generic products. The mandate of the committee was 1) to establish an official list of medications considered to be of satisfactory quality; 2) to selectively add medications to the official list which, in its opinion, were associated with long term and expensive therapy or which were of particular therapeutic value, and 3) to perform other functions needed to carry out its objectives. Throughout the period from 1968 to the present, the DQTC has been the catalyst in the continuing publication of biannual formularies, providing the expertise for the review of products to be included.

##### 4.1.1 Ontario Drug Benefit Formulary (ODBF)

The ODB plan, though complex, contains two fundamental components: the beneficiaries and the benefits. Since the Inquiry's views and recommendations regarding beneficiaries and access to prescription drugs are described elsewhere in this report, (see section 9.1) this section will focus on the benefits. In essence, these are announced through the Ontario Drug Benefit formulary (ODBF).

The formulary is significant both for the Ministry of Health (MOH) and, indirectly, ODB program beneficiaries, for it defines the drug

products, the cost of which the Ministry will reimburse. Various reports, briefs and comments have been directed to the Inquiry regarding the ODBF. While some of these have concerned only the biannual formulary publication itself, others have embraced the entire system encompassing drug product submissions by manufacturers, the review process for the purpose of selecting products for inclusion, and the way the ODBF is communicated to professionals.

A formulary—a compilation of available drug products—is not unique to the ODB program, but forms a part of most drug reimbursement plans throughout the world. In this province, the Ontario Hospital Association (OHA) promotes the establishment in each hospital of a pharmacy and therapeutics committee which develops and maintains a “formulary system.” This system is intended to encourage rational pharmacotherapy, discourage the use of less-than-optimal drug therapy, provide for generic selection and competitive bidding, and reduce inventories. The hospital formulary, the cornerstone of the system, is a continually revised compilation of drug products that reflects the best current clinical judgement of the medical and pharmacy staff. To be effective, the system must 1) have the approval of the organized professional staff; 2) establish broad policies relating to drug use in the institution, including the evaluation or appraisal of alternate drug entities, and the selection, procurement, storage, distribution, and safe use of drugs; and 3) provide both structure and flexibility so that comprehensive drug-use reviews and educational programs can become the norm. The MOH, with its ODBF and DQTC, operates a large-scale version of the formulary system found in most Ontario hospitals on a province-wide basis.

#### 4.1.2 The Formulary

Although the ODBF is euphemistically named the ‘formulary’, it is not a formulary in the usual sense of the word, but simply a list of drug product benefits. It encompasses those generic or nonproprietary names of drugs eligible for reimbursement, available strengths and dosage forms, and the drug identification numbers (DINs) which provide a code for specific manufacturers’ products, and an indication of cost for each product. Where more than one manufacturer produces a particular drug in a specified strength and dosage form, the formulary indicates which products are interchangeable. The legislation which mandates the MOH selective listing of products in the formulary, along with manufacturers’ and health professionals’ obligations, is the Ontario Drug Benefit Act (1986) and the Prescription Drug Cost Regulation Act (1986).

The current biannual ODBF publication is considered inadequate by many whose criticisms can be divided into two broad areas:

- the publication and its contents, and
- its role in drug utilization control.

There is every indication that, at present, the publication is only used in a very limited way by most prescribers. Although it informs the prescriber whether a particular product is a benefit, many physicians continue to be uninterested in or unaware of the cost of drug treatments. That the formulary is not more used by prescribers could reflect their lack of concern about cost issues, but it may also indicate that they do not find relevant and readily accessible information in the publication. In contrast to some formularies in other countries, it does not serve as a guide to the prescriber regarding common doses—particularly in the elderly—nor does it advise treatment strategies. Many professionals who use the present formulary complain that the publication is ‘unfriendly’, perhaps in part because of its style.

Nevertheless, the formulary appears to be of value to pharmacists by defining products for which reimbursement is offered and the amount of that reimbursement, and for determining the products that are interchangeable for the selection of inventory.

#### 4.1.3 Continuation of the Formulary

Although the formulary has played a fundamental role in the ODB plan, this Inquiry has seriously examined whether it is necessary for it to be continued. The question needs to be addressed from the different perspectives of the MOH, the pharmaceutical industry, the prescribers, the pharmacists and the beneficiaries.

For the MOH, the formulary is an inventory of quality products made available to the beneficiaries of the ODB. It contains a selection from the more than 5,000 products approved for sale in Canada by the federal Health Protection Branch (HPB), which has deemed them safe and effective; however, there is no consideration of relative merit in HPB approval, as there is in the Ontario formulary. The formulary is also a vehicle to control costs. Although an organizational structure that includes MOH employees and the DQTC is needed to maintain it, this cost—approximately 1 per cent of the overall cost of the program—is relatively small.

It is difficult to gauge whether the formulary, with its negotiated prices, has actually saved money with respect to the single-source products, for which there is no competitive alternative, listed as benefits. Perhaps some savings have been realized by excluding some new single-source products, or at least delaying their entry into the formulary if they are overly costly, have only marginal benefits and present a high use potential. However, the net financial impact of the exclusion of these products is not clear in terms of the cost of the use of alternate products in the short term, or

in terms of overall long-term health costs. With respect to multiple-source products, the designation of products as interchangeable has undoubtedly yielded substantial savings through competitive pricing.

Regardless, as described in section 3.2, the overall cost of the ODB plan has risen dramatically. In analyzing this rise, the Inquiry concludes that it is primarily attributable to increases in the number of claimants, the average number of claims per claimant, and the average cost of drugs per claim. That the third factor in itself accounts for nearly 50 per cent of the increase over the past decade suggests that the establishment of the formulary can only have been partially successful in containing costs.

There is no doubt that the formulary has had both positive and negative effects on the drug industry. Although it is the federal HPB that approves products for sale in our country, the listing of a given product in the Ontario formulary represents a 'good housekeeping seal of approval'. Other Canadian jurisdictions, and many Ontario institutions, such as hospitals, appear often to make local formulary decisions based upon whether a product is listed in the ODBF. Drug product advertisements in journals also frequently alert readers to its inclusion. To be listed, therefore, is an endorsement of the product and a form of promotion.

On the negative side, to be considered for approval by the MOH requires a new submission by the manufacturer, who has already gone through the steps needed for HPB approval, and another evaluation of the information, followed by the possibility of rejection. In addition, a formulary listing requires the price to be negotiated with the Ministry. Nevertheless, since listing in the ODBF means sizeable potential economic benefits, not to be listed can present a financial penalty and it is self-evident that manufacturers want their HPB-approved



products to be available for reimbursement in Ontario.

The ODBF has sometimes been viewed optimistically as a device to promote quality prescribing. Unfortunately, this alleged benefit appears to have been minimal because the mere listing of products does not necessarily lead to good prescribing. (Of course, the prescriber is affected by the formulary when the list of available benefits does not include products that are the prescriber's first choice. If the excluded products are, in fact, of questionable value in comparison to those available as benefits, it could be argued that the formulary does have a beneficial effect on prescribing.)

Prescribing a product which is not a benefit is possible, but the patient may be forced to pay for the medication out of pocket. Some physicians and dentists have regarded the formulary as an intrusion on their freedom to practice when all products approved by HPB are not considered as ODB benefits. Any form of additional prescribing control, such as the now defunct special authorization program, was seen as a further intrusion. Clearly, the elimination of the current formulary would permit all physicians and dentists to enjoy unbridled prescribing options for ODB beneficiaries.

As to pharmacists, the selective formulary presents certain advantages; for example, it reduces the range of inventory that must be stocked.

The beneficiary is only influenced by the formulary when his or her doctor or dentist wishes to use a product which is not a benefit, and this has already been considered above.

Therefore, although the present ODBF is only a minor factor in influencing prescribing, it does exert considerable control over costs, most notably through the listing of interchangeable products. There are deficiencies

in the present formulary, as cited in part above, which would point to the need for change. Two clear choices emerge: to eliminate the formulary or to alter it.

#### **4.1.4 Option 1-Elimination of the Formulary**

Since this Inquiry is recommending that a co-payment system be introduced for beneficiaries who can afford this (see section 9.1.6), there may be little need to preserve the formulary as another cost-controlling device. If it were eliminated, the marketplace could be expected to exert some control over the overall cost of drugs to the government. If the cost of the ODB plan increases beyond established limits, the government could counteract the effect by raising the co-payment fee and/or payment limit, in order to cap the overall cost of the plan. Any significant increases in either or both co-payment features would probably create pressure on prescribers and patients to reduce prescription drug use, with potentially dangerous consequences for those in need of drugs that become less available to them.

If the formulary were eliminated, all products authorized for sale in Canada by the HPB could be benefits, including products which at present have been excluded because they were considered unacceptable in terms of quality and/or cost. (Of course, increased use of these products would be seen by many as an undesirable outcome.) Disposing of the formulary would also have the benefit of eliminating the cost of the review process currently required for formulary inclusion.

If the formulary were discontinued, the MOH could still retain a powerful influence over drug use and costs. First, it could promote the use of interchangeable generic products, which clearly reduces the cost of drugs. The work of defining the interchangeable list could continue until such time as the HPB

assumes, for all of Canada, the role of officially assigning a bioequivalence rating to products given a notice of compliance. Second, new, unique and/or particularly costly products could be given special consideration and possibly restricted to controlled use in selected institutions. Third, the Ministry could still constrain the reimbursement cost of a drug product by requiring manufacturers to negotiate the provincial price. Fourth, the Ministry could establish a drug use review committee which would monitor prescribing patterns and, in a collaborative and collegial manner, work with the appropriate organizations to modify improper prescribing.

#### **4.1.5 Option 2 - Modifying the Formulary**

It appears that some drug prescribing is inappropriate at present. The elimination of the special authorization program, on our recommendation, which pared about 1,400 products from the unofficial list of benefits, was met with no great outcry. This suggests either that acceptable alternatives were found or that many of these prescriptions were unnecessary. The formulary still contains some products which, if reviewed again, would no longer be included. Generally, a product, once listed, has been retained, creating almost a “right” that manufacturers have come to expect. It is also clear that the present formulary makes no distinction among products within a therapeutic class, perhaps implying that they are all equally acceptable. Optimal pharmacotherapy, however, implies that the proper treatment strategy ordinarily begins with the use of cost effective first-line products, followed by more costly alternatives only when they are specifically required for a patient’s special needs. Some products, both because of their potential toxicity and/or low cost effectiveness, should legitimately be considered only after certain conditions become clearly evident in a given patient.

It appears logical then that for better treatment of ODB beneficiaries, the formulary, if retained, should be modified so that it becomes more dynamic. That is, at any point in time it should contain only those products which are still ‘state of the art’ as therapeutic entities. It should also encourage prescribers to select the optimal product from the list of available alternatives. This could be accomplished, in part, by designating some drug products for general use and others for ‘limited use’ based on specific risk/benefit/cost considerations. In order to put teeth into this two-tiered categorization, prescribers would need to be held accountable, particularly for their selection of limited-use products.

This option would mean that products would be scrutinized more closely and more regularly, and fewer would be retained in the formulary. This option, if adopted, would result in more adversarial confrontations between the Ministry and the pharmaceutical manufacturers and the DQTC would have to accept a much greater workload to cope with its product review activities. It would mean also that Ontario prescribers would have to adapt to more external intrusion into their respective practices. Many professionals can be expected to resent this, even though the quality of care is likely to be improved in the long run.

#### **4.1.6 Recommendations with Respect to the Formulary**

Of the two options presented, discontinuing the Formulary would undoubtedly receive the enthusiastic support of the manufacturers and most prescribers. Yet it would likely result in higher costs to the taxpayer, and would carry the potential for more inappropriate pharmacotherapy. The experience in hospitals is that the adoption of a local formulary discourages the use of less-than-optimal drug products.

Although eliminating the formulary does not preclude other ways of promoting rational prescribing—for example, through drug use review and professional education—it would take some considerable time and effort to make these as effective.

After considering all relevant factors, and giving particular weight to the need to encourage high quality pharmacotherapy, we have concluded that the public interest is best served by retaining, but modifying, the formulary.

**4.1 The Committee therefore recommends that an Ontario Drug Benefit formulary be retained but with significant changes.**

It is important that a new formulary be created from a zero base, without the expectation that any particular drug product now listed will necessarily be retained. That is, only those products with favourable benefit to harm and benefit to cost ratios would be listed.

**4.2 The Committee therefore recommends that after publishing the January, 1991 edition, the formulary be frozen in order to permit a new unencumbered formulary to be created. The benefits listed in the January, 1991 edition would therefore only continue until the publication of the unencumbered formulary, at which time all existing benefits would be terminated in favour of the new formulary benefits.**

During the interval between the discontinuation of the present formulary and the development of the new formulary, the MOH will need to make provisions so that any significant new therapeutic advances can be provided as benefits to ODB beneficiaries.

It is also recognized that a provincial formulary cannot contain all relevant drug and prescribing information. It has been recommended elsewhere that a new

publication ‘Medications of Choice’ be made available to guide prescribers in the rational selection of drugs (see section 7.2).

Nevertheless, the new formulary should be user-friendly, particularly to prescribers.

**4.3 The Committee therefore recommends that, beginning immediately, a review with respect to efficacy, safety, equivalence and cost of all products now listed in the formulary be initiated by the Drug Quality and Therapeutics Committee.**

At present the onus for launching the review process that leads to a product being listed in the formulary rests with the manufacturers: without a manufacturer’s submission, the product can not gain entry to the formulary. This is undesirable, for it means the DQTC cannot recommend that a drug be listed, even though it is considered to be an important therapeutic product.

**4.4 The Committee therefore recommends that mechanisms be developed to permit a drug product to be listed at the recommendation of the DQTC, even when no submission was initially made by a manufacturer.**

**4.5 The Committee also recommends that provisions be made to allow the formulary to take on a dynamic character; single and multiple source products should be regularly re-evaluated and then be retained, deleted or redefined by category.**

In view of the desirability of promoting optimal pharmacotherapy (see section 7.1), it is clear that prescribers should be held accountable for their selection of drug products. However, they must be permitted appropriate latitude in prescribing products not found in the new formulary for their ODB beneficiary patients when this is clearly in the patients’ interest.



**4.6 The Committee therefore recommends that the Ministry of Health, in cooperation with the College of Physicians and Surgeons of Ontario, the Royal College of Dental Surgeons, the Ontario Medical Association, the Ontario College of Pharmacists, and the Ontario Pharmacists' Association launch a program by January 1, 1992, that will monitor drug use and increase prescribers' accountability for their pharmacotherapy.**

Although the co-payment recommendation (section 9.1.6) allows the government to exercise some cost control over the ODB plan, the formulary can also exert an effect beneficial to the taxpayer, particularly through the listing of interchangeable products. Currently, although the federal government uses bio-availability data in granting the notice of compliance that permits a new drug product to be marketed in Canada, it does not make a statement about its interchangeability with other products. It would appear advisable that there be one national equivalence standard, rather than having various provincial or even regional jurisdictions duplicating efforts in this regard. However, until federal-provincial and inter-provincial agreement can be reached on a single national standard, the Ontario government will need to continue to identify interchangeable products (see also section 4.4.1). It is important to ensure that all products listed as interchangeable be of such quality that patients' therapy will not be compromised in any way when a new product selection is made by the pharmacist as a result of changes in the best available price (BAP) (see recommendation in chapter 5).

At present, some categories of products, notably the modified release dosage forms, do not offer competitive alternatives.

**4.7 The Committee therefore recommends that the development and use of multi-source products in non-conventional dosage forms be promoted where possible**

**by assembling and promulgating criteria which permit interchangeable products of non-conventional dosage or administration forms to be identified and listed.**

It is true that many prescribers specify 'no substitution' on their prescriptions because, as a result of personal preference or the promotional influence of the manufacturers, they believe the prescribed drug is superior. However, there is no substantiated evidence at present that patient treatment is compromised when other interchangeable products are used. Generic products are usually as effective and less costly than the brand name products with which they are interchangeable. In fact, when patients are hospitalized in Ontario it is likely they will be stabilized on a generic product if one is available. Efforts should be made to allay prescriber concerns about generic substitution while recognizing that in rare instances substitution is not indicated.

**4.8 The Committee therefore recommends that the Ministry of Health, the College of Physicians and Surgeons of Ontario, the Royal College of Dental Surgeons, the Ontario Medical Association and the Council of Faculties of Medicine work together to develop mechanisms to promote generic prescribing when this is appropriate.**

#### **4.1.7 The Process**

Through the Ontario Drug Benefit Act (1986), the Prescription Drug Cost Regulation Act (1986) and the attending regulations and guidelines, the Ontario government has set out the procedures and conditions for manufacturers to make submissions for formulary inclusion. It is important that manufacturers be clearly apprised of the criteria for the acceptance of products. Since we believe the recommended formulary should permit the

listing of desirable products, even when there is no submission by a manufacturer, it is important that manufacturers cooperate with the Ministry in furnishing information about products.

A new formulary is published every six months—July and January—and these deadlines have created a climate in which unnecessary tensions exist. Frequently there is a flurry of activity as manufacturers rush to submit the product dossier by the deadline date, and the Ministry and DQTC are pressured to meet time limits for the review process. With a deluge of submissions, the ability of the DQTC to make critical decisions about the relative merit of specific products is taxed. If the DQTC is not only to consider products for listing but also to recommend prescribing criteria for those products assigned to limited use status, a better system needs to be developed.

Manufacturers who fail to furnish key information by a deadline date are denied further consideration until the next formulary cycle. Because of time limits, they are sometimes also prevented from meeting with the Ministry or the DQTC to discuss important issues related to the product. This entire process is fraught with inadequacies and is in need of change. Time must be permitted for the review process and equitable opportunity must be given for fair consideration of manufacturers' concerns.

**4.9 The Committee therefore recommends that, after the January, 1991 edition, the Ministry discontinue the present system of formulary publication wherein bi-annual deadlines are specified and devise, in its place, a continuous system of product review.**

If this recommendation is adopted, the Ministry will need to determine a logical date for the publication of a formulary. Since the publication is not only associated with the

announcement of the benefits but also with the prices for product reimbursement, the Ministry will need to devise a new method of regularly announcing changes in both the benefits and prices.

The price of a drug product, particularly relative to other dosage forms or products in its therapeutic category, is an issue considered in the review process. It is worthy of note that a recent case involving a product submission extended beyond the MOH into the domain of the Ministry of Industry, Trade and Technology. It was argued that the true cost to government of a product should not be judged only by examining the best available price to the ODB plan, because factors such as taxes paid by the manufacturer, the number of Ontario employees, and investment in the province should legitimately enter the overall formula. It has been argued that this larger issue of overall benefit to the province should be examined closely so that all pharmacoeconomic factors are considered during the review of a drug product. Neither the Inquiry nor the DQTC have had the resources or the time to consider the interplay of broad economic benefits to Ontario with respect to specific drug prices. This general issue is considered further in chapter 5.

When a manufacturer receives word from the Ministry on the status of a particular product, opportunity is given for a reply and reconsideration if the product has been rejected. If the Inquiry's recommendations relative to a new formulary are adopted, manufacturers will potentially receive two notifications to which they may wish to respond: 1) a total rejection of a product for listing or 2) the relegation of a product to the limited use category. The new formulary, which can be expected to reduce the number of eligible products and assign others to limited use status, has the potential for increasing the adversarial relationship between manufacturers and the Ministry. Clear and fair guidelines will need to be established so that all parties understand the

negotiating process and know the boundaries and criteria for re-evaluation. Since the DQTC is assembled as an arms length expert committee to review drug products, it would appear unnecessary to create yet another panel of experts to serve as an appeal committee in order to rule on the expert advice of the DQTC.

## 4.2 DQTC

The DQTC plays a pivotal role in the review process which ultimately leads to the benefits announced in the formulary. As stated earlier, the first committee in 1968 was composed of seven members; currently it comprises 19 members appointed by Order-in-Council.

The Inquiry has received various comments regarding the DQTC. Not surprisingly, some claim the DQTC is redundant and the product review process is unnecessary because, in their view, this function is adequately fulfilled by the HPB, the federal regulatory body. Understandably, this opinion coincides with the view that the formulary is not needed. We have received no indication that the DQTC is considered to be unskilled in its product evaluation role. There is general support for the committee and, if anything, it has been recommended to us that the DQTC may be further strengthened by enhancing the perspective of the general practitioner in its complement of expertise.

### 4.2.1 Composition and Mandate

The committee is funded by, and is advisory to, the Minister of Health but operates at arms length. The Minister is free to accept or reject the advice received. Some view this veto power by the government to be unacceptable. However, by creating a committee that is purely advisory, the government assumes full responsibility for its decisions, which gives

the DQTC a measure of security. It seems unlikely that the committee would want to change this status and assume full responsibility and the risk of litigation.

The DQTC is composed of physicians, pharmacists and scientists, drawn from various parts of the province, who have the recognized expertise needed to review drug product submissions and advise the Minister. The terms of reference (1987) of the committee are wide-ranging and include:

- To advise the Minister on the operation of a program to assist the people of Ontario to obtain prescribed pharmaceutical products of quality at reasonable cost.
- To establish criteria to evaluate the quality and therapeutic value of drug products.
- To recommend to the Minister which drug products have met the prescribed conditions to be eligible to be designated as interchangeable products or to be listed in accordance with the Ontario Drug Benefit Act, 1986 and the Prescription Drug Cost Regulation Act, 1986.
- To evaluate pharmaceutical manufacturers and pharmaceutical products.
- To provide advice on relevant drug, pharmaceutical and therapeutic questions solicited or requested by the MOH from time to time.
- To review and assess information related to drug and pharmaceutical products prepared for the committee and for the Minister by selected consultants.
- To recommend, for distribution to the public and the health professions, information relating to pharmaceutical products and therapeutic topics.
- At the Minister's request, to act as liaison between the Ministry and professional, educational and other groups.



The committee extends its breadth and depth of expertise through a cadre of external consultants who are asked to furnish reviews and advice from time to time. It is also supported by technical and administrative personnel from the drug programs branch of the Ministry of Health.

#### **4.2.2 Recommendations with Respect to the DQTC**

Earlier in this section the need for a formulary was considered and we concluded, and recommended, that it be retained. It follows that the Ministry must obtain expert advice to decide which drugs should be contained in the formulary and in what categories, and which products are interchangeable. Alternatives to the DQTC can be envisioned but there are no compelling reasons which would dictate a change.

The concept of an advisory body of experts whose full-time employment is outside the government's bureaucracy has its benefits. The experts, some of whom prescribe the formulary benefits to beneficiaries of the ODB plan, bring along an external critique of the ODB plan and the drug programs branch, and carry back to their spheres of influence a more informed view on various facets of the program. In a limited way, this fulfills part of the hospital 'formulary system' described earlier, in which support for the formulary is mobilized among users.

**4.10 The Committee therefore recommends that an expert drug advisory committee, as represented by the present DQTC, be retained, with terms of reference similar to those already established, but modified as proposed in recommendation 4.11.**

It is essential that the DQTC and the Ministry work together closely and every effort must be made to safeguard a relationship of trust. For example, when the MOH fails to follow

the advice of its committee, reasons for the decision should be provided.

In view of our recommendations surrounding the new formulary, it will be important to retain the needed expertise to review all products in the present formulary. Since this would be a major new responsibility added to the normal review of product submissions, it may be necessary to seek further outside assistance, both from individual experts and from professional associations. This will enable the task to be completed in a reasonable time and will enhance support for the Ministry's final decisions about the listing of general and limited use products. Mechanisms for such additional outside assistance should be explored. The review process will also place greater demands on the drug programs branch staff, and the MOH must ensure that adequate technical and administrative support personnel are available.

The 1987 terms of reference enable the DQTC to respond to most of the responsibilities identified in our recommendations about the formulary. However, there are two issues that would suggest the need for a review of these terms. First, the comparative cost evaluation of products requires a more specific mandate concerning pharmaco-economic evaluation, particularly in the area of cost-effectiveness or cost-benefit analysis. At present the committee has neither the mandate nor the expertise for such evaluation. Second, in that we are recommending that the formulary be a dynamic publication, it will be necessary to monitor and evaluate the list of products in the light of drug use patterns, experience and scientific knowledge. It will also be important to evaluate the changes brought about by the new formulary. This supports the need for participation in drug use review (see section 9.2). However, it also suggests the need for specific research on the impact of formulary changes. At present the DQTC has no mandate or resources for such activities.

**4.11 The Committee therefore recommends that the DQTC's terms of reference be reviewed by January 1, 1991 and consideration be given to:**

- a) An expanded mandate that authorizes more effective evaluation of drug product cost factors; and**
- b) An expanded mandate, along with appropriate resources, that will permit the monitoring of the impact of formulary changes.**

The Inquiry has also been advised that there should be better communication between the Ministry and health care professionals regarding formulary developments. It is essential that health care professionals have a greater knowledge about what the DQTC does and why particular decisions have been made regarding product inclusions and exclusions and product interchangeability. If our recommendations regarding the new formulary are adopted there will be an increased need to acquaint health care professionals, in particular prescribers, with the criteria for using limited use products.

**4.12 The Committee therefore recommends that the Ministry and the DQTC become more active in regularly communicating with health care professionals about formulary benefits and the review process.**

## **4.3 Special Authorizations**

The recommendations regarding the special authorization (SA) program, as well as a longer version of the discussions leading to them, were first published in the second quarterly report of the Inquiry.

The Ontario Drug Benefit Act (1986 Sec. 8(1), Unlisted drugs, special case) provided authority for SAs. The program started in 1974

when the ODB formulary list was originally being created. The original intent was that only approved products were to be on the formulary list, and the numerous products on the market at the time made the task of choosing those drugs to be listed as benefits extremely difficult. If a product was not on this list, but was considered vital for good health care in a particular case, the prescriber could obtain an SA by making a telephone call to the program's executive director. The context must be remembered: there were relatively few beneficiaries under the plan; requests for drugs not listed in the formulary were infrequent; telephone approval was manageable. This changed in 1975 when ODB coverage was extended to all persons over 65 years of age; the SA program evolved rapidly from one which received a few informal calls from a limited number of physicians, to the extremely complex and expensive one of 1988.

Recent growth in the cost of the program had been alarming. As recently as 1979, the cost of the SA program was less than \$3 million; in 1987, the last reported year, there were almost a quarter million requests for products not listed in the formulary and the estimated cost was almost \$50 million. This program includes items other than drugs as well, namely oxygen and allergens, but the annual cost of drugs under the program had grown to about \$20 million.

The recent rapid growth in the cost of the overall ODB program can be attributed, in part, to the increase in the cost of the special authorization program: the portion of the ODB budget devoted to SAs has increased by 400 per cent in eight years, from less than 2 per cent of the ODB total in 1979 to over 8 per cent in 1987.

Approximately 2,400 drug products were listed in the July, 1988 ODB formulary; in addition, some 1,600 drugs had been granted SA status. In the process, SAs ceased to be

“special” as originally intended. The SA list had become a second “mini-formulary,” but without the safeguard of the products having to meet the criteria required for listing in the ODB formulary.

Some products which failed to receive approval after expert examination by the DQTC were nevertheless to be found on the SA list. This resulted in the anomalous situation where chemical entities which had been judged by a Ministry-appointed group of experts to be of very limited therapeutic value were paid for by taxpayers’ dollars under the SA program.

The absence of the cost-containing competition mechanism of interchangeability posed a further problem with respect to SA drugs. Interchangeability ordinarily ensures that residents of Ontario have access to high quality generic equivalent drugs at a lower price. But SA products were not construed to be benefits under the existing legislation for the purpose of determining interchangeability. Therefore, even when a generic product of apparent equivalence to one on the SA list existed, it could not be substituted (product-selected) by the pharmacist because interchangeability had not been evaluated or certified. In other words, the generic drug could not be substituted until an original drug was listed in the formulary and a generic drug was certified to be interchangeable.

The Committee was informed that this permitted some manufacturers to avoid generic competition. The loophole occurred when a manufacturer did not apply to the Ministry for approval of its drug product for formulary listing. In the absence of that first listing, no generic alternative, potentially interchangeable and available at lower cost, could be listed. In the meantime, the original, unlisted product was widely available and paid for by the taxpayer through the permissive SA program.

For these reasons the Committee strongly believed that the SA system was not acceptable. If a drug product is safe, useful and cost-effective it should be listed in the formulary. If it is not, it should not be eligible for reimbursement. The removal of these non-approved products from reimbursement status, or the imposition of special conditions on their use, should result in improved care for patients and lower drug costs for the taxpayer.

The Committee therefore made the following recommendations in its interim report of December, 1988:

**4.13 That the special authorization program be discontinued in its present form.**

**4.14 That all drug products to be authorized for payment under the Ontario Drug Benefit program be approved by the DQTC. (See recommendation 4.20 for the transition period.)**

**4.15 That all drug products authorized for payment by the Ministry of Health be listed in the formulary with specifications of the conditions, if any, under which they are eligible for coverage under the Ontario Drug Benefit plan.**

**4.16 That all drug products for which special authorization issuances have been granted be reviewed comprehensively by the DQTC. We further recommend that this be done in order of their frequency of use (commencing with the most commonly used), using the criteria required for formulary listing. All drugs approved by the DQTC after review should be listed in the formulary. Those drugs that fail to gain approval by the DQTC should neither be listed in the formulary nor be eligible for payment by the Ministry of Health**

**4.17 That the formulary contain two categories of drugs: *regular use* and**



*limited use*. The cost of regular use drugs should be reimbursed whenever they are prescribed and dispensed to persons eligible for Ontario Drug Benefit programs.

*Limited use* status may be granted to other drug products that will only be reimbursed under conditions determined by the DQTC and set forth in the Ontario Drug Benefit formulary. For example, *limited use* status may be granted when one or more of the following conditions apply:

- a) when the limited therapeutic conditions that were determined by the DQTC and set forth in the Ontario Drug Benefit formulary have been met;
- b) when *regular use* drugs have been tried and found ineffective, or have caused an adverse effect for a particular patient; and
- c) when alternative *regular use* drugs are contraindicated, due to concomitant therapy or to particular patient characteristics.

It would be the professional responsibility of the prescriber to verify that the condition(s) have been met.

4.18 That the conditions and restricted indications, if any, under which drugs will be authorized for reimbursement be clearly indicated. This may be done through appropriate footnotes or other means in the formulary.

4.19 That all drug products for which past special authorization issuances have been granted, once they are reviewed by the DQTC, be caused to fall into only one of the following categories:

- a) Formulary listing with regular use status;
- b) Formulary listing with limited use status; and

c) Ineligibility for reimbursement by the government of Ontario.

4.20 That during the transition period, until the DQTC is able to review drugs for which special authorization issuances have been granted, all current special authorization drugs awaiting review be permitted to maintain their special authorization status. However, there should be a strict moratorium on the addition of any new products to special authorization status.

4.21 That the DQTC establish a mechanism to expeditiously review new drugs which are major therapeutic advances.

The Committee did not recommend the specific procedures by which these recommendations were to be implemented.

The implementation of these recommendations should improve the quality of health care available to persons eligible for benefits under the ODB program. Drug products that do not meet the standards set by the DQTC would not be included as benefits. Limited use drug products that are demonstrably effective in certain clearly delineated circumstances would be benefits only if prescribed in that way.

Further, full implementation of these recommendations should reduce government expenditures for drugs. While the Committee cannot accurately predict the savings to the ODB program resulting from these recommendations, they are expected to be in the order of millions of dollars annually.

Implementation should also provide considerable administrative advantage to MOH staff, pharmacists, physician prescribers and nurses. The Ministry would not need to authorize and process SA requests; prescribers and their staff would not have to place calls to receive SA approval numbers. Pharmacists would not require the extra

reimbursement forms. The time saved should translate into both cost savings and increased professional productivity.

These recommendations were partially implemented by the Ministry, commencing in the summer of 1989. However, as this final report is being prepared a 'list of non-formulary benefits', containing many of the highly reimbursed products which were intended to be eliminated, persists. These products are still being reimbursed under the old procedures. Therefore, although the costs of the program have decreased, the monthly expenditure at the end of 1989, excluding oxygen and allergens, was still \$1.1 million, compared to \$1.7 million per month in 1988.

#### 4.4 Generic Drug Product Substitution

The Inquiry believes the quality of drug products, both innovative and generic, that are used in Ontario to be excellent. It is not necessary to examine this issue in greater detail but some problems with drug substitution deserve discussion.

In Canada the federal HPB is legally responsible for ensuring that drug manufacturers and their products fulfil the requirements of the Food and Drugs Act.

For new submissions, comprehensive data on toxicology, pharmacology and therapeutics of drug products must be submitted for review to the HPB. This includes extensive information on controlled clinical trials in four phases. In contrast to this extensive and expensive process, generic products only require evidence of bioequivalence, in addition to certain manufacturing data.

The HPB has recently published "Premarketing biopharmaceutical requirements."<sup>1</sup> The author, Dr. Mattok, stated that for a generic product the requirements will be limited to establishing that the rate and extent of drug absorption between the test and reference products do not differ by more than is judged to be clinically significant. Unfortunately the definition of just what is clinically significant seems not to have been examined. Rather, various measures of drug absorption as reflected by the AUC, Cmax and Tmax<sup>2</sup> have been utilized; since 1981, the guidelines have established an 80 per cent rule to indicate bioequivalence. In other words, the relative AUC must be between 80 per cent and 125 per cent of the defined standard, and that range is not deemed a clinically significant difference. Therefore the "equivalent product" must fall in the range 20 per cent below to 25 per cent above the standard.

Mattok states that the above criteria should apply to most drugs, but each drug product should be considered on its own merits. There is no information available to suggest that generic products currently marketed have been considered by any other criteria. In particular, there is no evidence that clinical studies have ever been required.

It is highly likely that for most types of drugs (eg. antibiotics) no clinical problems are likely to arise under these guidelines. However, for other drugs (where there are critical relationships between the plasma concentrations, bioavailability and clinical effect) the validity of these limits is untested. For example, a number of years ago, several digoxin preparations, where the bioavailability was not acceptable, were prevented from being marketed. Only one digoxin preparation is now marketed in Canada.

<sup>1</sup> Mattok, G.L. "Premarketing Biopharmaceutical Requirements," *Drug Information Journal*. 22:143, 1988.

<sup>2</sup> Area under the curve, maximum serum concentration, time to maximum concentration.

The HPB has the authority to utilize an expert advisory committee on bioavailability, but for many years this committee has been inactive. Only recently has the committee begun developing criteria for designating the bioequivalence of various dosage forms.

Because of these and other issues, the MOH has chosen to rely on the DQTC to advise on questions of interchangeability. Generic drug product substitution has saved Ontarians very large sums of money (see section 5.1), and considering the enormous number of prescriptions for which generic substitution has been made, there have been relatively few problems.

The present program in which the DQTC advises on the status of interchangeable drug products applies only to Ontario, but we believe that a similar system would better serve all Canadians. Because health care services are primarily a provincial responsibility in Canada, and the main impetus for generic substitution programs is the economic benefit which accrues to the provinces rather than to the federal government, this is difficult to achieve. The potential benefits in cost-savings, however, are obvious. We are recommending (see recommendation 5.1) that the government of Ontario take the lead in promoting federal-provincial and inter-provincial agreement for a single Canada-wide policy and standard regarding drug interchangeability.

Product selection by pharmacists, or substitution of one brand of product for another, can cause problems for some patients, although this is rare. Isolated cases of adverse reactions have been reported when patients stabilized on one product were given another brand of the same drug. Such reactions have occurred with changes from generic to brand name product, from brand to brand, from one generic to another and from

brand to generic. In 1987 the Ontario Medical Association (OMA) council approved the following recommendations: "That for patients undergoing repeated or prolonged pharmacotherapy, the OMA recommends that physicians write 'no substitution' on such prescriptions" and "that the OMA requests pharmacists ensure that patients receive the same pharmaceutical product on an ongoing basis for prolonged pharmacotherapy." This problem continues to cause concern to physicians and their patients.<sup>3</sup>

It seems that the concern lies in the switching of products, rather than an inherent problem with the generic or the innovator drug. It is very difficult to reconcile an unlimited taxpayer-supported "no-substitution" policy while attempting to maximize the economic benefits of using the lowest price equivalent. The "best buy" for the pharmacist may vary from month to month; hospitals buying in bulk may get an especially good deal on a product that may not necessarily be the one used by community pharmacists filling a repeat prescription for the patient after discharge from hospital. These issues are especially important when new generic products are introduced.

Consumers are surely entitled to know what medications they are taking and we have received many submissions making the point that patients should be informed when product substitution occurs. Without this information, neither patient nor physician can properly assess changes that might, or might not, be medication related. It may be that many anecdotal reports of adverse drug reactions following product substitution are analogous to placebo effects, but they are no less important for that. While largely undocumented, some reactions may potentially be attributable to excipients (non-pharmacological substances in the product) and to bioavailability differences.

<sup>3</sup> Mahon, W.A. and Druck, M.N., *Cardiovascular Update*, June 1989, pg. 15-18.s



The Committee has carefully considered the conflicting advice we have received concerning generic product substitution, and has concluded that, on balance, the present Ontario government policy is in the best overall public interest. Moreover, except for rare situations, it is our conclusion that the substitution of drug products that have been judged by the DQTC to be interchangeable does not reduce the quality of pharmacotherapy, although it clearly does reduce the cost of the drug program.

**4.22** The Committee therefore recommends that while the present Ontario policy of drug interchangeability, which promotes generic drug substitution and price competition, should be continued:

a) The Ontario College of Pharmacists direct pharmacists to refill prescriptions with the same product as originally dispensed when its price is equivalent to competing products. (It is understood that when there is a substantial price difference, pharmacists will dispense the drug product priced at the level at which they will receive reimbursement.)

b) “No-substitution” prescriptions no longer be included as benefits under the ODB plan; where the patient requests that the specific product prescribed be dispensed, the patient should pay for the difference in price above the lowest cost product for which the pharmacist will be reimbursed.

c) The Ministry of Health, on the advice of the DQTC, establish a mechanism whereby a physician can request that a specific product be permitted as a benefit (the cost of which would be fully reimbursable to the pharmacist) for those very rare situations where a particular patient cannot tolerate or benefit from the lowest priced product.

d) Policy and, if necessary, legislation be altered to require pharmacists to inform both patients and prescribers that product substitution has occurred.

e) When a new generic preparation first comes into general use, the Ministry of Health require the generic manufacturer to publicize appropriate information to prescribers, as innovative manufacturers now do.

#### **4.4.1 Interchangeability – Product Selection**

The bulk of section 4.4.1 was found in the third quarterly report of the Inquiry.

When brand name products have been marketed for a period of time and have proven commercially successful, the drugs will often also be made available in “generic” versions. These are usually, though not always, manufactured by companies other than the ones which introduced the primary products. The MOH has the advice of the DQTC, which reviews these drugs and determines which of them are interchangeable. If, in the expert opinion of the DQTC, two or more products with the same chemical composition of active ingredients produce very similar effects in human beings, they are considered interchangeable. This determination of interchangeability is made when either the bioavailability of the products (e.g., drug blood levels) and/or the clinical therapeutic effects are sufficiently similar so as to be virtually identical.

An important landmark in the history of Canadian drug programs was reached in 1972 when Ontario amended the Pharmacy Act, permitting pharmacists to dispense one or other of interchangeable products, a process called “product selection.” The government of Ontario accepted the legal responsibility of ensuring the therapeutic equivalence of interchangeable products.

If two or more products are determined to be interchangeable it is clearly desirable, in most instances, to select the least expensive product; experience in the marketplace has shown that when more than one version of a drug becomes available the price falls.

The regulations pursuant to the Ontario Drug Benefit Act, 1986 and the Prescription Drug Cost Regulation Act, 1986, specifically permit pharmacists to substitute a lower priced product that is deemed interchangeable for a specific product that a physician prescribes. Because the ODB plan will only reimburse pharmacists for the lowest priced drug of two or more interchangeable products, the pharmacists have a powerful incentive to dispense the least costly product.

A limitation results from the wording of the 1986 legislation,<sup>4</sup> according to which interchangeability can only be determined if at least one of the products is currently listed as an Ontario drug benefit.<sup>5</sup>

Therefore, the substitution cannot be made at the present time if the product has not been listed in the formulary. The extension of interchangeability to the right to substitute non-formulary products would result in savings for consumers at large; they would have more situations in which, on the advice of their physicians and pharmacists, they would be able to choose between equivalent products of different prices.

Representations to the Inquiry in submissions from certain companies and associations (for example the Canadian Drug Manufacturers' Association and Apotex Limited) have urged that the issue of interchangeability of drug products be separated from that of availability as a benefit under the ODB program. If the DQTC were empowered to make recommendations with respect to the appropriateness of interchangeability of two or more drug products, the purpose of those recommendations should be irrelevant. It should make no difference whether or not a product is to be listed in the formulary, because decisions with respect to interchangeability are not logically or therapeutically related to the decision to have a drug paid for by the ODB program.

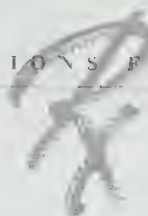
**4.23 The Committee therefore recommends that the DQTC be empowered to review applications and make recommendations to the Minister of Health with respect to the interchangeability of drug products independent of the status of the products as benefits under the Ontario Drug Benefit program. If it is deemed necessary to change the legislation or regulations to make this possible, the appropriate change should be initiated.**

<sup>4</sup> "Each product that is listed in Schedule 1 of a particular strength and dosage form of a drug is interchangeable with each other such listed product.", O. Reg. 690/86, s.2, and "In this Regulation, 'original product' means the original source of a drug product in a particular strength and dosage form that is designated as a listed drug product under Ontario Regulation 689/86 (General) or that was listed as a drug product in the PARCOST C.D.I. prescribed under Ontario Regulation 839/84;" O. Reg. 690/86s. 1, pursuant to the *Prescription Drug Cost Regulation Act*, S.O. 1986. C. 28.

<sup>5</sup> A benefit is defined as a product, listed pursuant to the Regulations to the 1986 Acts, for which the government will reimburse the pharmacists if the person for whom it is prescribed is an eligible beneficiary; the list of such benefits is the Ontario Drug Benefit formulary.







## Chapter V

### Acquisition of Drugs

*Chapter 5 examines both innovative and generic drug manufacturers and the growth and profitability of the industry. It discusses the best available price concept and makes recommendations relating to drug pricing. The chapter also recommends a limited formulary for smaller hospitals, nursing homes, homes for the aged and community practice.*

#### 5.1 Role of Manufacturers

##### 5.1.1 Structure of the Manufacturing Industry in Canada

The structure of the pharmaceutical manufacturing industry in Canada has been largely determined by the way in which manufacturers respond to federal patent and drug approval legislation. Chemical entities, including pharmaceuticals, are usually discoveries patentable under federal legislation. Legislation in most of the western world's countries provides for patenting of chemical discoveries, but the exact provisions vary according to the jurisdiction. Generally, a company which has discovered or received a license for a pharmaceutical chemical will protect it by patent in the major western nations and will seek to maintain the market exclusivity granted by patent protection for as long as possible.

The health service authorities of most countries also impose a procedure for obtaining approval of the chemical before it is marketed. Establishing proof of safety and efficacy takes many years of complicated and expensive testing and review. Because of the

enormous costs of developing, registering and marketing original pharmaceuticals,<sup>1</sup> most manufacturers of new chemical entities are multi-national companies, largely based in the United States, Europe and Japan (see table 5.1).

The Canadian industry is composed primarily of Canadian subsidiaries of the large multinationals, as shown in table 5.2. The last large domestic manufacturer of innovative pharmaceutical products, Connaught, recently sold controlling interest to the Institut Merieux, a Rhone-Poulenc subsidiary from France.

For historical reasons Canada, accounting for approximately 2 per cent of the total western world market, has no independent manufacturers of original pharmaceuticals and the local industry consists mainly of manufacturing and distributing subsidiaries.

At the same time, it is of interest that Canada's pharmaceutical market has been growing faster than the average rate for the western world. According to Scrip,<sup>2</sup> the international newsletter of the industry, the 1989 world market increased about 13 per cent over 1988; Canada's market increased 16 per cent over

<sup>1</sup> The costs to discover and develop a new drug are, on average \$150 million, according to the brief by Rhone-Poulenc (# 24-A-3200). This is confirmed by a statement that it costs more than US \$125 million, in Scrip, Review Issue 1989, p.1.

<sup>2</sup> Scrip: World Pharmaceutical News, PJB Publications Ltd.: London, Review Issue 1989, p.7.

Table 5.1

**Top 15 Pharmaceutical Companies Worldwide, 1988-89<sup>1</sup>**

Company	Pharma sales (\$ mill) <sup>2</sup>	% change <sup>3</sup>	Pharma and total sales
Merck & Co. (U.S.)	4,983.7	+17.9	83.9
Glaxo (UK)	4,577.8	+35.7	100.0
Hoechst (WGer)	3,958.0	+12.7	17.0
Bayer (WGer)	3,712.6	+20.8	16.1
Ciba-Geigy (Switz)	3,531.7	+11.4	29.3
Takeda (Japan)	3,471.4	+26.6	64.8
Am Hom Prod (US)	3,218.0	+10.0	58.5
Sandoz (Switz)	3,147.0	+15.5	45.4
Eli Lilly (US)	2,679.8	+12.5	65.8
Abbott (US)	2,599.0	+11.4	52.6
Pfizer (US)	2,539.0	+8.9	47.1
Warner-Lambert (US)	2,509.0	+11.2	64.2
Bristol-Myers (US)	2,508.8	+13.2	42.0
Eastman Kodak (US)	2,500.0	NA <sup>4</sup>	14.7
Roche (Switz)	2,410.2	+16.3	40.6

<sup>1</sup> Figures are for the year ended December 31, 1988, except Glaxo (June 1989) and Takeda (March 1989);

<sup>2</sup> Dollar conversions are based on average annual exchange rates for 1988;

<sup>3</sup> Percentage change in US dollars over previous year;

<sup>4</sup> Pharmaceutical sales relate to Sterling Drug, which was acquired by Kodak in February 1988, and figures for the previous year are not available.

Source: Scrip, Review Issue 1989, p.8.

the same period, at a time when the world economy only grew by 4 per cent. The growth rates and estimated values of different markets are listed in Table 5.3.

Due to the nature of patent legislation, the manufacturing industry is divided into two main groups: innovative and generic.

In the **brand-name** or innovative drug manufacturing segment, patented pharmaceutical products are manufactured by the inventor, or by firms licensed to sell the product by the inventor.

In Canada, federal legislation was introduced in 1969 that obliges manufacturers to grant

compulsory licences to import and sell pharmaceutical products to firms which pay royalties to the holder of the patent. This compulsory licensing legislation was responsible for the growth in Canada of that segment generally known as the **generic** drug industry, which manufactures and sells generic versions of chemical entities which have large enough markets to justify duplication. In Canada, the companies in this segment of the industry are largely Canadian-owned manufacturers of generic versions of medications whose patents have expired, as well as those which are still under patent but for which the company has received a compulsory license.

Table 5.2

**Corporate Ranking 1988  
Pharmaceutical Companies**

National	Ontario
1. Glaxo	1. Glaxo
2. Nordic	2. Apotex <sup>1</sup>
3. Merck	3. Novopharm <sup>1</sup>
4. Wyeth	4. Nordic
5. Squibb	5. Merck
6. Geigy	6. Squibb
7. Apotex <sup>1</sup>	7. Merrell Dow
8. Novopharm <sup>1</sup>	8. Geigy
9. Parke Davis	9. Wyeth
10. Merrell Dow	10 Parke Davis

<sup>1</sup> Canadian-owned companies.

According to the first annual report of the federal Patented Medicines Prices Review Board (PMPRB)<sup>3</sup> the total factory gate<sup>4</sup> sales of the pharmaceutical manufacturing industry in Canada were \$3.1 billion in 1987, which represented retail sales of approximately \$5.9 billion. These figures include medicines under patent as well as off patent, medicines for both human and veterinary use, and both prescription and over-the-counter medicines. Of the \$3.1 billion factory gate sales, roughly 32 per cent, or \$1 billion, represented sales of the 423 patented drug products on the market. The \$1 billion sales are divided into different markets: community pharmacy 34 per cent, wholesaler 31 per cent, hospital 28 per cent and other 7 per cent.<sup>5</sup>

Generally, the companies that form the brand-name or innovative segment of the industry belong to the Pharmaceutical Manufacturers Association of Canada (PMAC). "The 41 members that constitute the Ontario chapter of PMAC provide employment for 9,000 Ontarians. In 1985 they had sales revenue of

more than \$1 billion, held assets of more than \$980 million and paid \$97.6 million in taxes to government and \$305 million in wages and benefits to Ontario employees."<sup>6</sup>

The generic segment of the industry is spear-headed by two major firms, both located in Ontario, and several smaller companies, most of which belong to the Canadian Drug Manufacturers Association: "There are currently 21 member companies—11 in Ontario, nine in Quebec, and one in British Columbia."<sup>7</sup> Although exact sales figures are unavailable because the two major companies are privately owned, Canadian sales in the generic segment are about \$380 million,<sup>8</sup> or approximately 8 per cent of total Canadian factory gate sales. The structure of the

Table 5.3

**World Pharmaceutical Market  
Estimates, 1988**

Market	(\$ Million) Estimated Market Value	Percentage World Market	Percentage Growth
United States	17,900	28	15
Japan	15,100	23	6
West Germany	5,300	8	8
France	4,400	7	16
Italy	4,300	7	15
United Kingdom	2,300	3	13
Canada	1,500	2	16
Spain	1,500	2	16
Rest of world (exclusive East Block)	12,700	20	21
Total	65,000	100	13

Source: Scrip, Review Issue, 1989, p.7.

<sup>3</sup> Patented Medicines Prices Review Board, *First Annual Report 1989*, p.3-4.

<sup>4</sup> This includes sales to distributors as well as sales to hospitals and retail or community pharmacies.

<sup>5</sup> PMPRB, Annual Report, 1989.

<sup>6</sup> PMAC brief, #114-3100, p.5.

<sup>7</sup> CDMA brief, #53-3100.

<sup>8</sup> IMS Canada, Share of Market by Region—Drugstores, January to June 1989. The generic companies included in this total are : Apotex, Novopham, Horner, Technilab, ICN, Pharmascience, Prodoc and Drug Trading. Total annual sales in Canada are quoted there at \$5,747.3 million.



Ontario Drug Benefit (ODB) plan reimbursement system in Ontario is such that sales of generic products hold a higher segment of the market in this province, totalling 14 per cent.<sup>9</sup>

The pharmaceutical industry in Canada is profitable. In terms of performance and profitability, compared to other industry segments, the pharmaceutical industry rates highly, as illustrated in table 5.4.

Relative to manufacturing in general, the industry utilizes fairly low fixed assets compared to its equity investment. The cost of sales is less than 50 cents on the dollar, compared to a total manufacturing industry average of almost 80 cents, and profit after tax on equity is nearly 25 per cent, compared to a manufacturing industry average of less than an 11 per cent. This pattern has been consistent over the years; more than 30 years ago "Dr. John M. Blair, the chief of the Federal Trade Commission division of economic reports (U.S.), presented the following ...as a comparison of rates and returns after taxes in selected industries (1957):

Drug	21.4
Petroleum refining	12.8
All manufacturing	11.0" <sup>10</sup>

Internationally, the pharmaceutical industry is also one of the highest performers. As can be seen from Table 5.3, international market growth has been high: 13 per cent for 1988 over 1987. Leading individual companies have performed even better than that, as can be seen from table 5.5.

Although wholesale distributing issues are discussed in detail in chapter 6, a brief discussion at this point will augment the description of the structure of the industry. Although many of the manufacturers in Canada have their own distribution systems and sell directly to hospital and retail

pharmacists, roughly half of the products sold to pharmacies in Ontario are distributed through wholesale distributors. (Generic manufacturers generally distribute directly; no general rule applies to the brand-name manufacturers.) The largest distributor in Ontario is a cooperative owned by pharmacists. Although some manufacturers predominantly distribute either directly or through wholesalers, almost all will do some of each and the proportions vary.

Manufacturers sell drug products to two major types of buyers, retail pharmacies and hospitals, either directly or through wholesalers. These marketplaces differ quite radically. Many of the drugs sold to hospitals must be administered by injection, rather than taken in oral form. The drug costs of hospitals are not paid directly by the province, but form part of the global budget of the institution. Often hospitals purchase by way of tender, or group purchasing committees negotiate terms for member hospitals. The Ontario Hospital Association (OHA) and Carecor (the Metro Toronto group of hospitals) have purchasing programs for their members; these are, respectively, Hospital Purchasing Program (HPP) and Hospital Purchasing Inc. (HPI). This subject is examined in greater detail in section 5.2.

In Ontario, individual pharmacy owners are responsible for the purchasing decisions for their stores; in the case of chains, the central purchasing group may assist. Even for the largest chain stores, drug purchases are not made by way of tender and the actual terms of purchase are not regulated by the province. At the same time the province has considerable indirect influence on purchase price and terms because it reimburses pharmacists for those products on the list of eligible benefits for beneficiaries of the ODB program (see section 4.1).

<sup>9</sup> Ibid.

<sup>10</sup> Klass, Alan, *There's Gold in Them Ther Pills*, Penguin Books: U.K., 1975, p.75.

Table 5.4

Selected Corporation Ratios, 1986						
	No.	FA/ <sup>1</sup> EQ. <sup>2</sup>	CoS/ <sup>3</sup> SLS <sup>7</sup>	PAT/ <sup>4</sup> CAP. <sup>5</sup>	PAT/ EQ.	PAT/ INC. <sup>6</sup>
Pharmaceuticals	132	40.5	49.6	22.7	24.8	9.5
Total Chemical and Chemical Products	1179	74.8	69.4	5.6	8.1	3.9
Total Manufacturing	43161	70.6	79.9	7.8	10.8	4.3
Total Non-Financial Industries	403742	104.9	77.5	4.9	8.2	3.1

1. Fixed Assets, 2. Equity, 3. Cost of Sales, 4. Profit After Tax, 5. Capital Employed, 6. Total Income, 7. Sales.

Source: Statistics Canada, Corporation Financial Statistics, 1986, Cat. 61-207.

However, the terms of sale with respect to the manufacturers are regulated by the province. Manufacturers submit prices to the government for listing in the formulary, but the best available price (BAP) can be confirmed through other sources of information. BAP is defined as the lowest price for which that product is available in Canada for sale in Ontario. The Ontario Ministry of Health (MOH) has the authority to investigate manufacturers, wholesalers and pharmacists to ensure they are complying with the requirements of the legislation by submitting accurate price data.

If they have been found to contravene the Act, manufacturers may be penalized by having the formulary price lowered or the product "delisted" from the formulary. Pharmacists, who are reimbursed at BAP, are understandably reluctant to pay the manufacturer more than the listed price. As a consequence, for those products which are listed, the price set by negotiation between the MOH and the manufacturer tends to be the Ontario-wide, non-hospital price for the product. This process affects most of the drug products sold through pharmacies in the province, as very few drugs which are not listed in the formulary succeed in gaining an appreciable share of the community market.

## 5.1.2 Federal Regulation and Influence on Market Structure

**5.1.2.1 Health Protection Branch:** To be legally marketed in Canada, a drug must be approved for sale by the federal Health Protection Branch (HPB) of Health and Welfare Canada. [There are exceptions; for example, drugs which are undergoing testing in Canada may be sold in limited circumstances under the Emergency Drug Release program.]

The approval process for new drugs is complex. Prior to commencing any clinical trials in human subjects, the manufacturer must obtain the permission of the HPB. The first step is the "preclinical new drug submission." The supporting documentation for this includes all chemical composition and manufacturing details, as well as the results of all laboratory and animal studies performed. There are three phases of clinical trials. Phase I trials are those performed among a small group of healthy human volunteers; phase II trials involve a small group of individuals suffering from the disease or illness the drug is intended to treat; phase III trials are performed among a large group of people with the disease or illness.

Table 5.5

**Top Pharmaceutical Companies Worldwide by Profitability, 1988-89<sup>1</sup>**

Company	Profit (\$ millions)	Sales (\$ millions)	Margin (percentage) <sup>1</sup>
Zenith	18.8 <sup>6</sup>	28.4	66.2
Connaught	86.0 <sup>5</sup>	150.5	57.1
Ares Serono	128.5 <sup>2</sup>	353.2	36.4
Beecham	687.9 <sup>3</sup>	2,006.1	34.3
J&J	789.0 <sup>2</sup>	2,338.0	33.7
Merck & Co.	1,806.2 <sup>4</sup>	5,473.4	33.0
Abbott	773.0 <sup>2</sup>	2,599.0	29.7
Eli Lilly	968.7 <sup>2</sup>	3,271.8	29.6
Egis	50.8 <sup>6</sup>	171.8	29.6
Warner-Lambert	725.0 <sup>2</sup>	2,509.0	28.9

1. Profit as percentage of sales; 2. Operating profit—Eli Lilly's figures relate to the human health segment; 3. Trading profit; 4. Pre-tax operating profit —Merck & Co's figures relate to human and animal health products; 5. Pre-tax profit; 6. Net profit.

Source: Scrip, Review Issue 1989, p.8.

An important part of the process is the approval of the product monograph, a document which lists the indications, contraindications, side-effects, dosages, etc. This information is required by the physician or dentist in order to properly prescribe the product. Changes to the ways in which the drug is to be used, including the addition of indications for which the drug is appropriate (adding an indication will increase the market for the product), or other changes in information contained in the monograph, must be first approved by the HPB. Monographs are thus periodically updated as newer and different indications for the drug product are discovered, side-effects are updated and dosage information is changed.

Problems with the approval system and the monograph procedure were reported in the review of the HPB<sup>11</sup> and discussed in the press by Lexchin.<sup>12</sup> The approval process for changing monographs is cumbersome; the procedure is slow and changes may take years to receive approval. Manufacturers whose products are showing promising additional indications (which would result in increased sales) have an incentive to have the monographs changed; there is a corresponding disincentive to the manufacturer to apply for the indications for use of a product to be limited. However, the HPB can require changes in the product monograph, if it determines that there are sufficient reasons for so doing.

<sup>11</sup> Program Evaluation Study of the Drug Safety and Quality Evaluation program of Health & Welfare Canada, p.6.

<sup>12</sup> The Toronto Star, Tuesday, September 26, 1989.



Approval procedures by the HPB are frustratingly lengthy although a recent review<sup>13</sup> concluded that the length of the process is not unconscionable. The manufacturer's wish to start to sell the product must be tempered by the exercise of caution to ensure the Canadian public is protected from unknown adverse drug reactions.<sup>14</sup> The longer approval is delayed, the more reports will become available from other countries where the product is utilized.

The approval requirements for brand name and generic products are different: the innovative brand name product requires extensive clinical studies and many types of tests which confirm its safety and efficacy.<sup>15</sup> The generic drug, which is merely a similar formulation of an existing product which has previously been approved for marketing, requires much less in the way of evidence. Generally the human trials required for generic products are limited to studies by which the manufacturer shows that the product is bioequivalent, or absorbed and eliminated from the human body in the same way as the originator's product.

The federal and provincial jurisdictions play different roles with respect to determination of bioequivalence and drug approvals. "HPB interprets its mandate as one of *verifying* that the safety and efficacy *data* contained in the submission [from the manufacturer] meet the requirements of the Act and Regulations. This does not specifically constitute certification of the safety and efficacy of drug *products* approved for marketing in Canada."<sup>16</sup>

Ontario guarantees product quality through legislation that requires the government to assume legal liability for the substitution of one brand of drug product for another when both are included in the formulary listing

interchangeable products. The information gap between what Ontario requires for this guarantee of interchangeability, and what the HPB provides by its approval process, has been filled by an advisory group of experts called the Drug Quality and Therapeutics Committee (DQTC). Decisions about product listings and interchangeability are made by government, which may accept or ignore the advice of this group. The DQTC, among other things, will review the manufacturer's data and make specific determinations of whether or not two brands of drug are bioequivalent. On occasion DQTC has refused to confirm as equivalent certain products which have received approval from the HPB.

**5.1 The Committee therefore recommends that the government of Ontario take the lead in promoting federal-provincial and interprovincial agreement for a Canada-wide interchangeability policy. Health and Welfare Canada should be given a wider mandate: in addition to confirming the safety and efficacy of drug products, the approval process should also include a determination of whether the product is bioequivalent to, and interchangeable with, other approved products.**

**5.1.2.2 Patent Legislation:** The amendments to the Patent Act which were embodied in Bill C-22, which came into effect December 7, 1987 "...contained provisions restricting the use of compulsory licences. These licences are not to be exploited or used for pharmaceutical products for seven to 10 years after the drug has been approved for sale by Health and Welfare Canada, depending on the circumstances. ...Patentees can thus be assured of a period of at least seven to 10 years where they have the exclusive right to market a drug product in Canada. This period is called the period of exclusivity. It is during this period

<sup>13</sup> Op cit., Program Evaluation Study.

<sup>14</sup> Ibid., p.6.

<sup>15</sup> The active chemical ingredient is the same in the generic and brand-name product. The other ingredients—fillers, coatings, colours, preservatives, etc., known as excipients—may be different. The excipients generally have no effect on the action of the active chemical ingredient of the medicine.

<sup>16</sup> Op cit., Prog. Eval. Study p.8.

that normal market forces are most constrained, thus creating the greatest potential for excessive prices. However, if the board [PMPRB] determines that a patented medicine is being sold at an excessive price, it may restore the potential for competition by removing the Bill C-22 prohibition on the use of a compulsory licence on the medicine in question and, optionally, on one other of the patentee's medicines. Alternatively, the board may order a reduction in the price of the medicine in question to a level determined not to be excessive."<sup>17</sup>

Prior to the Bill C-22 amendments, the generic manufacturers could apply for and obtain a compulsory license for a product and market it at any time after its approval. Since the generic brand is generally priced below the equivalent brand-name product, this change in legislation means the province will not benefit from the lower prices for generic versions of new products for several years. New drug products which become listed as benefits in the formulary, and which can be expected to be widely prescribed, will therefore not have generic competition for at least seven years. This will have the effect of increasing the total drug benefit cost: generally, newer drugs are priced much higher than the older products they replace in a particular therapeutic category. The shift to newer, higher priced products, as well as the addition of a new drug to the prescribing arsenal for an illness or disease which could not be treated previously by a drug, will result in increased costs.

Of course, it may also result in improved health care. Moreover, when an illness is treated more effectively by a new drug there may be savings in other health care costs. An example of this was the marked decrease in the cost of surgery and hospitalization which resulted from the treatment of peptic ulcers by the first of a new class of anti-ulcer drugs.

However, predicting savings from the introduction of new drug products is difficult. The successful treatment of a disease by a medication (or any other intervention) will result in increased costs in the long run, as the treated individual usually lives longer to benefit from additional health care services. Also, a product such as the anti-ulcer drug may be found useful in treating conditions and symptoms in addition to those originally treated by surgery. The net effect may well be both improved treatment and higher costs.

### 5.1.2.3 Patented Medicines Prices Review

**Board:** When Bill C-22 was enacted to extend effective patent life, the PMPRB was set up to review the prices of patented products so as to ensure that these are not excessive. The PMPRB reports annually on the general price trends of drugs, and on the research and development expenditure ratios of the patentees and the industry.

According to guidelines published by the board, price increases are deemed excessive only if they exceed the original December 7, 1987 price by more than the annual consumer price index.<sup>18</sup>

The prices of products first marketed after that date are reviewed depending upon the way the board categorizes them:

- new versions of existing drugs (usually additional dosage forms or strengths of medicines already being marketed) will be compared directly to the current price per kilo of the active chemical;
- breakthrough drugs, or drugs which represent substantial improvements over older products, will be compared to the prices of all drugs in the same therapeutic class, and to the median international price;

<sup>17</sup> Patented Medicines Prices Review Board, First Annual Report 1989, p.5.

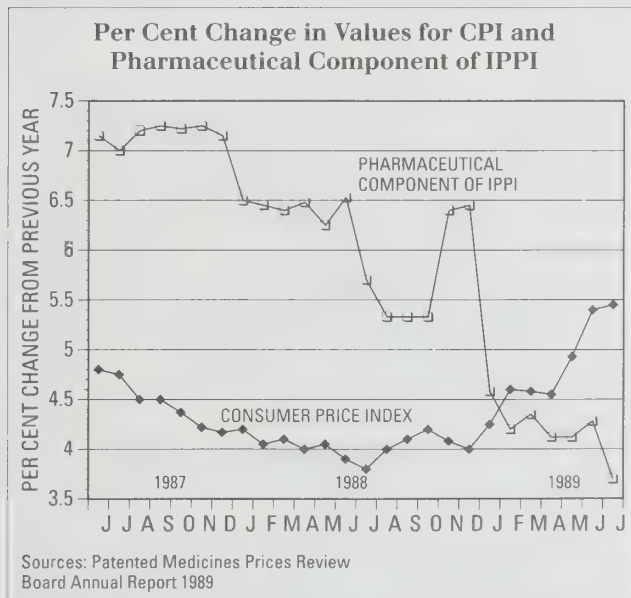
<sup>18</sup> Patented Medicines Prices Review Board, "Guidelines: Excessive Price", July, 1988, p.2.

- new drugs which are not breakthrough drugs, or substantial improvements over older products, will be compared to the prices of all drugs in the same therapeutic class;

And if the new price is not greater, it will be deemed not excessive.<sup>19</sup>

This process will likely have the effect of containing future increases in the price of medicines. In the recently published first report of its review of prices, the PMPRB indicated that, by January 1989, the pharmaceutical component of the industrial products price index, IPPI, which before the board's guidelines were promulgated had been roughly 2 per cent above CPI, has fallen to below CPI.

Figure 5.1



However, the effect on the drug price component of the annual cost of the ODB plan will not necessarily be the same. The mix of drugs prescribed and reimbursed changes as new medications and new forms of existing medications become available. When physicians

are convinced that a new drug is even marginally better than older ones in a therapeutic category, they will tend to prescribe the new drug even though it is costlier.

It can be expected that:

- if the newer product is a new dosage form, it will likely replace a generic product which had competed successfully with the previous form of the brand-name drug; it will be priced at the same general level as the previous brand-name product form, which will generally be higher than the price of the generic product;
- if the newer product is a new drug, but not a substantial or breakthrough product, it will likely be priced near the top of the therapeutic class; it will again likely replace a generic product priced nearer the bottom of the therapeutic class;
- finally, if the product is a significant improvement, it will replace one for which there may have been a generic product, but the new price will be governed by the median international price; the replaced product will have been priced somewhere within the therapeutic class, which is likely to be below that of the median international price of that product.

### 5.1.3 Provincial Regulation and its Influence on Market Structure

A multiplicity of structures, which evolved because of differing provincial regulations, have been added to the federal regulations. The provinces have considerable influence on the behaviour of the industry because they play a powerful role in the way in which drugs are acquired. The larger the provincial share of the Canadian market, of course, the greater the impact is felt nationally. Quebec

<sup>19</sup> Patented Medicines Prices Review Board, Bulletin, July 1989, pages 4 to 6.

<sup>20</sup> Health and Welfare Canada, *National Health Expenditures in Canada 1975-1985*, Ottawa, 1987.



and Ontario combined consume over 60 per cent<sup>20</sup> of Canada's drugs, contain the head offices of almost all the manufacturers, and host 91 per cent of the pharmaceutical research and development performed in Canada.

There is constant pressure from the manufacturers on the two provincial governments to make the economic and political climates more conducive to the development of the industry. The associations representing the companies, and the individual companies themselves, attempt to apply pressure by threatening to move operations and research funds if their interests are not dealt with sympathetically. This situation has existed for years, and there is no reason to believe it will change radically in the near future. The industry's requirements for a large pool of highly skilled labour for manufacturing and university centres for research make a major shift within the country unlikely, even over the longer term. The industry will continue to be centred around Montreal and Toronto because the resources it requires are limited elsewhere in Canada, and because of the capital investment already made in these metropolitan areas.

Among others, the one criterion the industry considers in determining the location of investment is the differing regulations of the two provinces. The Ontario regulatory environment was discussed in detail in chapter 3, and a brief discussion of the Quebec environment follows.

The Programme de médicaments du Québec has a formulary (Liste de médicaments) which contains the products eligible for coverage by Quebec's plan. The products are listed in the Liste for "regular" or "exception" use, the latter applying to drugs where special authorization is required for reimbursement.

The concept limits some products from being drugs of first choice, but allows their use when other drug therapy is not appropriate. The decisions to include products in the "Liste" are made by a professional advisory group, le Conseil consultatif de pharmacologie. The reimbursement level for a product is the price in the Liste, or what amounts to the manufacturer's suggested list price. The Programme will reimburse the pharmacist up to the median price listed in the formulary for multiple-source products or, in certain circumstances, the maximum price listed. Priorities are offered to products manufactured in Quebec, providing the price is not more than 10 per cent greater than the median, which is the reimbursable amount unless the prescription is one of no-substitution. The legislation also allows the pharmacist to dispense a lower-cost interchangeable, although this is not mandatory.

Recently, price increases for products listed in the Quebec formulary have been restricted to the level of CPI. Formulary listings are based on the safety and efficacy of the drug as well as the cost with reference to the therapeutic advantage.<sup>21</sup> The political influences on the provincial formulary are evident in the recent example of Famotidine, listed in the July, 1989 with the following footnote: "Ce médicament, dont le Conseil consultatif de pharmacologie avait recommandé l'inscription comme médicament d'exception pour des motifs d'ordre budgétaire, a cependant été inscrit à la liste régulière des médicaments conformément à un décret gouvernemental en raison de retombées économiques." [This drug, which the council had recommended be listed as a drug of exceptional use because of budgetary reasons, was nonetheless included in the regular use list in conformity with a governmental ruling for reasons of economic returns.]

<sup>21</sup> Number 35 of the Liste states on page G.1 G.2: "Normes et critères de sélection des médicaments...12. Pour une même voie d'administration, l'inclusion dans la liste de différentes présentations pharmaceutiques d'un médicament est basée sur le coût de ces présentations en regard des avantages thérapeutiques; 13. L'inclusion dans la liste d'un médicament ayant un effet thérapeutique marginal est fonction du coût de ce médicament."

Quebec's approach is more laissez-faire when compared to Ontario's more interventionist role in the drug marketplace over the last two decades, as outlined in chapter 3. The industry perceives the Quebec position as much more favourable and considers it more conducive to establishment and growth. For example, the Inquiry was told that: "Pfizer Canada has a deep commitment to Ontario, illustrated by its research and development expenditures in the province in 1987/88. The company is committed to increasing overall R&D spending to reach 10 per cent of sales by 1995. However, this pledge to research and develop in the province is made with a degree of misgiving about the investment environment in Ontario. Provinces such as Quebec are offering attractive incentives to manufacturers who locate facilities in their province. Pfizer Canada's tradition of investment in Ontario is now becoming more difficult to maintain in light of investment opportunities elsewhere, but more importantly due to the less than hospitable environment being created by the Ministry of Health and Bills 54 & 55."<sup>22</sup> This sentiment was echoed by many of the manufacturers, including Rhone-Poulenc Pharma Inc.<sup>23</sup>

Chief among Ontario's interventionist policies which concern the innovative industry is the product selection mechanism that encourages price competition in the marketplace, discussed in detail in chapters 3 and 4. To reiterate briefly, the Ontario drug program only reimburses the pharmacist for the lowest-priced equivalent product. The effect has been to increase the market share of the generic manufacturers in Ontario, and to create considerable savings for the provincial government program, particularly in instances where more than one generic product exists. This cost saving has been at the expense of the brand name manufacturers whose share of the market declines markedly when generic drugs are selected by pharmacists.

The sequence of events which creates competition in the prescription drug marketplace is as follows: An innovative manufacturer receives HPB approval for a drug product. Through advertising, promotion and detailing of the product to physicians (and minimally to other health care professionals, including dentists and pharmacists), that product becomes more or less accepted by the medical profession, and gains a certain share of the market in its therapeutic class. The manufacturer also submits the product to the DQTC for approval and inclusion in the Ontario formulary. As indicated in chapter 4, inclusion in the formulary has a tremendous effect on the share of the market which will be taken by a product. The ODB staff negotiates prices and price increases for products listed in the formulary, but the drug manufacturer can control the negotiations for single-source products. The lowest price negotiated for interchangeable products is the price the ODB pays for all prescriptions dispensed for any of them.

If a product is reasonably successful during the period of patent exclusivity, one or more of the generic product manufacturers will be interested in manufacturing an interchangeable product once the patent protection ends. The manufacturers will make application and receive approval from the HPB for their version of the product, and will be able to sell it, either when the patent of the innovator's product expires, or at the effective date of the compulsory licence received by the generic manufacturer. The generic manufacturer will apply for listing in the formulary from the DQTC, which will usually designate the product as interchangeable with that of the innovator. The generic manufacturer stands to gain the highest financial return from a product during the time when it is the only generic equivalent product listed in the formulary.

<sup>22</sup> Pfizer Canada Inc., brief #146-5200.

<sup>23</sup> Rhone-Poulenc Pharma Inc., brief #24-5200.

Table 5.6

**Price of Lowest Generic Unit Price\* as a Percentage of the Highest Brand Name Price:  
Selected Drugs (By Formulary)**

Drug Name	Jul. 87	Jan. 88	Jul. 88	Jan. 89	Jul. 89	Jan. 90
Zantac 150mg Apo-Ranitidine	74.64%	71.09%	74.52%	76.42%	76.4%	76.4%
Cardizem 60mg Apo-Diltiazem				81.8%	74.13%	76.3%
Cardizem 30mg Apo-Diltiazem				81.85%	74.14%	76.3%
Halcion .25mg tab Triaxolam				87.55%	87.55%	75.0%
Tenormin 50mg tab Apo-Atenol				78.59%	78.65%	78.6%
Entrophen 650 mg tab Novasen	89.54%	89.64%	89.64%	89.35%	89.29%	88.8%
Timoptic .5% OphSol Apotimoptic			75.06%	74.2%	72.84%	73.9%
Zantac Apo-Ranitidine	74.71%	71.5%	74.63%	76.52%	76.52%	72.9%
Cephulac o/1 Acilac	74.81%	79.95%	80.72%	80.72%	83.5%	79.7%
Tenormin 100mg tab Apo-Atenol				78.77%	78.77%	78.8%
Aldactazide 25mg tab Novo-Spiriozine	104.46%	100.00%	100.00%	104.97%	97.14%	102.0%

\* unadjusted

Source: ODB/CDI Formulary

The reimbursement mechanism works to the advantage of the generic manufacturer because the pharmacist, who is reimbursed only at the BAP, will dispense the generic product in all situations where the prescription is for an ODB beneficiary, unless it is a “no-substitution” prescription. Brand-name

manufacturers will rarely compete with a generic manufacturer on price. Their usual marketing techniques focus on attempting to persuade prescribers to issue “no-substitution” prescriptions for their product because of its purported advantages.



**Table 5.7**

**Price of Lowest Generic Unit Price\* as a Percentage of the Highest Brand Name Price:  
Selected Drugs (By Formulary)**

<b>Drug Name</b>	<b>Jul. 87</b>	<b>Jan. 88</b>	<b>Jul. 88</b>	<b>Jan. 89</b>	<b>Jul. 89</b>	<b>Jan. 90</b>
Adalat 10mg cap Apo-Nifed Novo-Nifed			69.3%	69.03%	73.93%	70.4%
Dyazide 25 & 50mg tab Apo-Triazide Novo-Triamzide	44.75%	46.99%	45.2%	46.4%	47.36%	45.2%
Ativan 1mg tab Novo-Lorazem Apo-Lorazepam	54.47%	57.25%	66.76%	70.00%	71.41%	71.4%
Feldene 200mg cap Apo-Piroxicam Novo-Pirocam	54.49%	54.48%	54.48%	57.04%	55.47%	52.8%
Clinoril 150mg tab Novo-Sundac Apo-Sulin			74.99%	77.85%	77.93%	75.14%
Amoxil 250mg cap Novamoxin Apoamoxin	43.52%	54.8%	54.80%	54.80%	55.93%	53.2%
Robitussin o/l Guaifeneson Guaifeneson-Sugarless	42.68%	47.30%	42.94%	42.61%	41.85%	42.6%

\* unadjusted

Source: ODB/CDI Formulary

Several examples of the formulary listing prices are found in table 5.6. As can be seen, if only one generic is listed the price will generally fall between 75 and 85 per cent of that of the innovator's product. For example, Cardizem 60mg is listed in the January, 1990 formulary at .5986 per tablet. Apo-Diltiaz, the generic interchangeable, is listed at .4568, or 76 per cent of the Cardizem price.

Large savings for the ODB program do not occur until at least two generic products are competing to establish the BAP. Examples of prices where there is more than one generic interchangeable product are found in table 5.7. For example, the listed price per capsule for Feldene 20 mg in the January, 1990 formulary, is 1.3562. Novo-Pirocam 20mg is listed at .7514 and Apo-Piroxicam 20mg at .7156, or 53 per cent of the price of Feldene.

At present generic manufacturers who arrive first on the market and in the formulary are guaranteed at least six months' head start in competing for the sizeable ODB market for their product, because the formulary is issued semi-annually. If approval of the second generic product is delayed, the advantageous market position is effectively extended for at least a year.

"...in terms of the total number of prescriptions in Canada, [the two leading Canadian-owned generic companies] are no small lightweights. They ranked number one and two with market shares of 11.9 per cent and 6.6 per cent respectively in 1988... While the entire Canadian market grew by only one per cent in 1988, the two leading generic firms grew by 6 per cent and four per cent respectively. It has been projected that, as existing patents expire over the years ahead, the generic sector will be able to grow three times as fast as it has in the past in Canada."<sup>24</sup>

Since costs and marketing expenses of generic products are relatively low, and the market can be sizeable, the Committee feels that recent initial generic prices have been unnecessarily high.

**5.2 The Committee therefore recommends that a generic equivalent of a brand-name product not be listed in the formulary for the first time at a price which exceeds 60 per cent of the reference price of the equivalent brand-name product. That reference price will be the listed price of the brand-name product found in the formulary immediately prior to the one in which the generic product is to first appear.**

The marketplace in Ontario is dominated by the price level scheme predicated on ODB reimbursement. But there is also room for decision-making by consumers and their physicians, based on considerations other

than the basic ones of equivalency, quality and cost made by the DQTC. If ODB beneficiaries or their physicians, for whatever reason, choose to take or prescribe products other than the ones available at BAP, they should have that option, upon paying the price differential to the pharmacist.

**5.3 The Committee therefore recommends that all prescriptions for multi-source products to eligible beneficiaries, whether or not they are inscribed by the prescriber as no-substitution, ordinarily be reimbursed only at the lowest "best available price" for the product. If the pharmacist, at the request of the patient, dispenses a product for which the listed price exceeds BAP, the patient must pay the difference to the dispensing pharmacist. The pharmacist may be reimbursed for a no-substitution prescription of a higher-priced product only when the prescriber has an approved reason for this. (See recommendation 4.22)**

#### **5.1.4 Economic Influence**

**5.1.4.1 Investment:** The government of Ontario has to consider the overall economic benefits derived from the pharmaceutical industry according to several criteria. Government policy must determine which industries are best for the provincial economy and which it therefore wishes to attract. The "bottom line" is the economic return to the province for the cost of attracting and keeping that investment. As a major purchaser of drug products, directly or indirectly, the government also has a strong interest in controlling drug prices. The trade-off occurs when the government balances the advantage of keeping drug prices low against the advantage of creating a climate in which drug manufacturers will wish to invest in research and manufacturing activities in Ontario.

<sup>24</sup> PMAC advertising supplement to the December 11, 1989 issue of Macleans Magazine, p.14.

The analysis of costs and benefits, in terms of attracting investment and saving purchasing dollars, will include both the generic and the innovative segments of the industry. The two must be examined in tandem, as policies that encourage the growth of one segment have tended to be detrimental to the other. The analysis is complex and this Inquiry has neither the time nor the expertise to appropriately analyze and balance the implications of policy alternatives in this area. We understand that steps are being taken to perform such an analysis.

However, the government, the manufacturers themselves and available research have all provided information with respect to the funds spent currently on purchases and on investment.

On the one hand, Ontario is the largest single ultimate "purchaser" of drugs in Canada. We use the term purchaser even though hospital drug costs are contained in their global budgets, and even though the drug programs branch of the MOH acts as reimbursor of drug costs for those Ontario residents who qualify as beneficiaries under various programs. Each policy with respect to the beneficiaries, and each benefit which they receive at government expense, affects the total amount billed to the Ontario government, and paid by Ontario taxpayers. On the other hand, both financial and human capital are invested by the drug industry in production and in-house research and development, as well as research at Ontario universities, and the Ontario economy benefits considerably.

A study done for the Eastman report<sup>25</sup> estimated that the increased use of generic products sold in pharmacies and hospitals because of compulsory legislation resulted in total savings of \$211 million in Canada in 1983. This total was derived from an analysis performed on a basket of drugs. The ODB

program, as purchaser, accounts for more than 13 per cent of total Canadian sales (\$191.7 million of \$1.461 billion total Canadian pharmacy sales in 1983).<sup>26</sup> The 1982 saving to the Ontario government was \$27.64 million, or 14.4 per cent, and if that percentage is still applicable to the current ODB expenditure, the saving from generic product use is now \$51.91 million on drug costs of \$360 million. If the percentage is applicable to total Ontario pharmacy sales of \$1.0887 billion, the saving resulting from generic product use is \$156.8 million per year.

The approximate balances are as set forth in table 5.8.

In countries which have innovative drug manufacturing industries that make significant contributions to national research and product development, the nation's interest may be served when the innovative side of the industry is favoured over the generic. For countries such as Canada, with a modest indigenous innovative drug industry, it is far from certain that this is the case.

Following the passage of federal Bill C-22 in 1987 there may be a greater incentive for investment in innovative drug research and development in Canada. Ontario has an excellent university-based research potential. In particular, Ontario faculties of medicine are now very positively disposed towards industry/academic collaboration in research. We have received many well reasoned submissions from Ontario universities, and the innovative industry, providing evidence of recent expansion of research facilities and plans for their development. How strongly to support the generic side of the industry, which also provides jobs and contributes to Ontario's well being, is clearly a *political* rather than a health care decision.

<sup>25</sup> *Report of the Commission of Inquiry on the Pharmaceutical Industry*, (The Eastman Commission Report), Ottawa, 1985, p.316.

<sup>26</sup> *Ibid.*, page 80.



Table 5.8

### Ontario Industry Segment Comparisons

	\$millions R and D	Employment	\$millions Sales <sup>1</sup>	Wages	\$millions Savings <sup>3</sup>	Savings <sup>4</sup>
PMAC Companies	72	9000	936	305	0	0
CDMA Companies	0	1000	152	34 <sup>2</sup>	52	157

Source: <sup>1</sup> IMS Canada, Drugstore, 1988.

<sup>2</sup> Estimate only, based on averaging PMAC wages over 1000 employees.

<sup>3</sup> Based on acquisition costs of drugs reimbursed for ODB plan.

<sup>4</sup> Based on acquisition costs of all drugs in Ontario.

**5.1.4.2 Research and Development:** Since the implementation of the federal legislation extending the period of patent life exclusivity, the patent holding manufacturers have been increasing the percentage of sales spent on research and development. Most of this money, with a few very noticeable exceptions, is going into clinical rather than basic research.

Canada has not historically been known for high levels of research and development by pharmaceutical manufacturers. "The characteristic strategy of [major international firms] is to carry out much of their basic research near their headquarters...Thus, U.S. firms, which dominate the Canadian market, do 85 per cent of their research in the United States, and most of the rest in the United Kingdom, West Germany, and France. European firms carry out a higher proportion of their research in foreign countries and the favoured location for foreign research is in most cases the United States....The location of significant research in the pharmaceutical industry is principally determined by the location of the parent firm's headquarters, which itself reflects historical evolution of specific skills and interests in that firm and

the general scientific infrastructure of the country, but is also affected by the degree to which the host government is willing to aid pharmaceutical enterprises by heavy subsidies, tolerance of high prices, and support of relevant science in universities and institutes."<sup>27</sup>

The federal Eastman Commission analyzed the level of research and development carried out by the firms in Canada, and conducted a survey which established levels of investment and expenditure.

Research and development expenditures in Canada have been gradually increasing according to reported statistics: from \$10.4 million in 1967, to \$57 million in 1982, to 157.55 million in 1988. The ratios of R&D to factory shipments have been increasing only recently: from 3.5 per cent in 1967, to 3.8 per cent in 1982, to 6.1 per cent in 1988.<sup>28</sup>

The recent increase in the ratio of R&D to factory shipments has been a result of the impact of Bill C-22, which extended patent protection in Canada and carried with it some promises by the industry. Among these was the promise to increase the level of R&D to 8

<sup>27</sup> Ibid., p.423.

<sup>28</sup> Ibid., p.62.

per cent by 1991 and 10 per cent by 1996. This latter figure will bring Canada only up to the average international level. The current level of R&D is estimated at 6.1 per cent to national sales;<sup>29</sup> and 8 per cent to Ontario sales.<sup>30</sup>

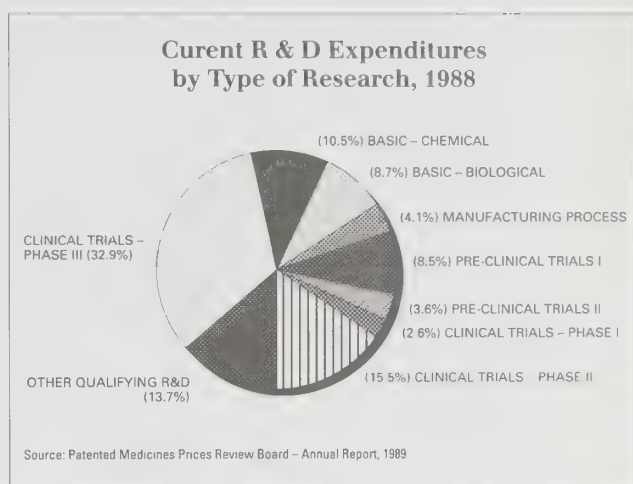
R&D in Canada (figure 5.2) consists largely of clinical research, or research which involves testing of drugs in human subjects, which must be done to obtain marketing approval for the product.

Of the total \$157.55 million spent on R&D in 1988, 63 per cent was for clinical and pre-clinical trials. However, the percentage devoted to basic research has risen quite sharply since last reported in 1983. "...in 1983, approximately 15 per cent of research and development expenditures by pharmaceutical firms in Canada were devoted to basic research, a proportion that was slowly rising from 1979..."<sup>31</sup> We now have reports that nearly 20 per cent of our R&D is invested in basic research, so this area has been increasing much faster than the total invested in R&D. "Worldwide R&D spending is estimated at about (\$16 billion), on sales of (\$160 billion) with about 80 per cent of the expenditure accounted for by the US, Japan, the UK, West Germany, Switzerland, France, and Italy. 85 per cent is spent on new chemical entities, and the ratio of development to research spent is two-thirds/one-third..."<sup>32</sup>

### 5.1.5 Advertising, Promotion and Education

When discussing the industry and the regulatory systems, it is important to distinguish between the two types of product on the market: single-source and multi-source. The pricing and selling mechanisms are entirely different for these.

Figure 5.2



**5.1.5.1 Single-source Products:** A single-source product is one for which there is only one manufacturer and one brand. These products are still protected by patent and cannot be manufactured under compulsory licence; alternatively, if the patent protection has expired, they have a sufficiently limited market that more than one brand is not judged profitable. The exceptions to this are those products which are not interchangeable; digoxin is an example of this type of product, as are sustained-release products, although the status of the latter is currently under review by the DQTC. A discussion of this issue is found in chapter 4.

A pharmacist who receives a prescription for a single-source product has two main options: to dispense the prescription with the product on hand or ordered for quick delivery, or to turn the patient away and give the business to another pharmacist. A less commonly-used option is to attempt to influence the prescribing decision; that is, for the pharmacist to convince the physician to change the prescription to another product. In the majority of cases, the pharmacist follows the first option and dispenses the product.

<sup>29</sup> Patented Medicine Prices Review Board, First Annual Report 1989. This represents a total research and development expenditure of \$164.5 million and sales of \$2.7 billion.

<sup>30</sup> 45.52% of the total Canadian research and development costs as reported by the Patented Medicines Prices Review Board in 1988 were spent in Ontario, or \$71.5 million.

<sup>31</sup> Ibid., p.422.

<sup>32</sup> Scrip, Review Issue 1989, p.1.

Therefore, for a single-source product, the point of sale is when the physician makes the decision to prescribe it for a specific indication in a specific patient. The thrust of manufacturers' marketing and sales efforts for single-source products will be to influence the physician to prescribe the product in as many situations as possible.<sup>33</sup> The intended result of these efforts is to have the physician choose the particular product over other products that could be prescribed for the problem under management. This, of course, presumes that the physician has the appropriate information and can bring it to bear quickly given the pressures of his or her particular practice.

Manufacturers claim that the majority of the money they spend on advertising and marketing is for the purposes of educating and informing physicians about the proper uses of products. But this cannot account for the entire amount expended on advertising, free sampling and entertaining of physicians; much appears to be for promotional purposes in order to gain the highest market share and sales volume possible. Several of the presentations to the Inquiry dealt with promotion to physicians, and this issue is dealt with in chapter 7.

In an article about information services provided to physicians by manufacturers,<sup>34</sup> the assertion that brand-name manufacturers supply better information to professionals than do generic manufacturers, is challenged. This study was "...to evaluate both research-based and generic pharmaceutical companies with regard to the rapidity and adequacy of their responses to a physician's request for information about a drug interaction."<sup>35</sup> The study discovered no significant difference between the responses.

Because of the importance of physicians as prescribers, most industry expenditures for advertising, promotion and marketing of drug products in Canada are directed to the physician and, to a very small extent with specified products, to the dentist. Recent information shows these costs to be approximately 25 per cent of sales.

For the sale to finally take place, however, the product must be actually acquired by the patient for whom it is prescribed. In situations where the patient pays for the drug out of pocket, the issue of affordability enters the decision process. In situations where the patient has third-party insurance benefits, affordability is of less concern. The main financial issue will be one of cash flow, or "up-front" affordability, if a co-payment is required. Financial considerations generally do not enter into the decision-making process when the patient is covered by the ODB program, because the patient receives the prescription product "free" and the pharmacist is reimbursed directly by the government. Price, therefore, enters into the marketing and sales program of a pharmaceutical manufacturer in a way not generally experienced with other consumer products.

Although drug programs, third party insurers and consumers are all sensitive to total costs of drugs or drug programs, they are less sensitive to the price of individual products. In general, a high value is placed on drugs—as is the case with all health care need—and manufacturers need not be particularly concerned with economic sensitivity when it comes to single-source products. In addition, because the "sales" decision is in two parts—the person who chooses the product (the prescriber) is not the same as the person who pays for it (the patient, the insurer, or the

<sup>33</sup> Based on total sales of \$2.3 billion, the PMAC reports its members spending 25 per cent, or \$589 million, on marketing and sales. This represents an average of \$6,674 per professional (physicians, pharmacists and dentists), or, if pharmacists and dentists are excluded, because the physician is the prime target, over \$10,000 per physician.

<sup>34</sup> Lexchin, Joel, and Martin Thomas, "Pharmaceutical Manufacturers' Responsiveness to Physicians' Requests for Information: A Comparison of Brand and Generic Companies," Proceedings of the Second Annual Health Policy Conference, Research and the Health Policy Process Conference, Centre for Health Economics and Policy Analysis, Hamilton, June 1 and 2 1989, pp.197-205.

<sup>35</sup> Ibid., p.197.



Ministry) —the issue of price only affects the second part and rarely enters into the decision to prescribe. Not all physicians are aware of the costs of drugs, because many patients, particularly those over 65, generally do not pay for them themselves.

In Ontario, price sensitivity for single-source products has only recently entered the ODB system, because it is only since the Prescription Drug Cost Regulation Act, 1986 that the Ministry has been negotiating price with the manufacturers. Decisions made by the DQTC to recommend for or against listing a particular product have only recently included cost as a criterion.

In Ontario the major indirect “purchaser” of all single-source products prescribed for consumers and dispensed to them is the government itself. There is little incentive for other players to enter into price negotiation with manufacturers. Consumers, prescribers and dispensers are essentially neutral with respect to price. Manufacturers, wishing to optimise returns, have no incentive to minimize price because the volume sold is relatively inelastic with respect to the price charged. The only player with an incentive to reduce prices is the purchaser—the Ontario government.

The government, as purchaser, is extremely limited in the way in which it can influence price where the product is single-source; any influence on the manufacturer is exercised in a voluntary negotiation process. The manufacturer is aware that the only effective negotiating tool available to the province is to refuse to list a product in the formulary if the price is too high. But sales volume is heavily influenced by whether or not the product is listed in the formulary. Manufacturers know that physician prescribing can be influenced by their patients, and a major influence on patient behaviour is whether the patient has to purchase a particular drug him- or herself or will be able to receive it free of charge.

The listing of a product in the formulary will have a major effect on the market share of that product within its therapeutic class.

The government should use its influence to attempt to negotiate the lowest possible prices for single-source products, taking into account their benefits and costs when compared to other products available in the same therapeutic class. Comparisons of costs relative to demonstrated effectiveness could be used by the DQTC in its reviews of listings of products, and be included in determining whether products should be listed and generally available, only available on a limited basis, or not listed as a benefit at all.

**5.4 The Committee therefore recommends that the concept of best available price be maintained, in preference to other forms of definition of reimbursement price to pharmacists.**

To summarise, the brand-name pharmaceutical industry appears to be in sound economic shape. It is over twice as profitable as the average industry in Canada, spends only an average of \$4 million to develop a new drug for the Canadian market (based on the 2 per cent share of the world market found in Canada), has exclusive control of that market under the new patent legislation for seven to 10 years, and spends 25 per cent of its sales on marketing and promotion.

The Committee believes that the Ministry should use the listings in the formulary to hold price increases to reasonable limits. As indicated, drug price increases have been above CPI. We therefore propose price increase restrictions for products listed in the formulary, both for general and limited use. If the manufacturer fails to agree to these recommendations, the product should not be listed in the formulary and should not be reimbursed if prescribed for persons eligible to receive ODB.

**5.5 The Committee therefore recommends that the price for reimbursement of all drugs in the January 1991 formulary be rolled back to the price at which they were listed in the December 1986 formulary, plus consumer price index increases from December 1986 to January 1991. If the product was not listed in the December 1986 formulary, its January 1991 price should be rolled back to the price at which it was first listed after December 1986 and then increased to a value no greater than that allowed by the increase in the CPI from that date to January 1991. If the CPI adjusted price is higher than the current price, the current price should stand.**

We have recommended contributions from various health care professions and from consumers which are both financial and educational. Manufacturers, as stakeholders in the industry, should also be expected to contribute to improving the prescribing and utilization of drug products by making a financial contribution.

**5.6 The Committee therefore recommends that, for the period commencing with the formulary which follows the January 1991 formulary and ending in January of 1994, increases of drug prices listed for reimbursement shall not exceed 50 per cent of the consumer price index.**

Manufacturers of single-source products have little incentive to service the pharmacist, as the point of sale is the physician. Therefore, government should use its influence as reimbursing body to negotiate the terms on which products must be made available to the end user, if the product is to be or remain listed in the formulary. The BAP should, as currently defined by legislation, be the net of all deals and incentives. As a condition of listing, manufacturers should undertake to make available that product size on which BAP has been determined, at that listed price, to all pharmacies or wholesalers. This undertaking should be for the duration of the applicable formulary.

The Committee was also told about the increasing spread which has entered the pricing system under the current BAP negotiated reimbursement mechanism. The recurrence of the very situation the new legislation was intended to eliminate must not be tolerated. The legislation, as it now reads, does not prohibit the pharmacist from claiming reimbursement at a level higher than that which was actually paid for the product. It seems that this spread will continue to be a problem for the system unless both the manufacturer and pharmacist are held accountable, and until there is no incentive to make deals which lower the cost, without passing on those savings to the reimbursing body.

**5.7 The Committee therefore recommends that the current legislation be amended, with appropriate sanctions, to strengthen the "best available price" concept so that manufacturers are required to sign a binding agreement to make available that product size on which BAP has been determined, at that listed price, to all pharmacies or wholesalers for the duration of the applicable formulary.**

**5.8 The Committee further recommends that the Ministry of Health vigorously pursue allegations of deals and incentives provided by manufacturers in order to immediately reduce the "best available price" accordingly, if the allegations prove true.**

**5.9 The Committee further recommends that the legislation be amended to prohibit pharmacists from claiming reimbursement (for the cost component of the prescription price) under Ontario Drug Benefit at a level higher than that which was actually paid for the product.**

**5.10 The Committee also recommends that the legislation be amended to require pharmacists, when dispensing prescriptions for interchangeable products in the non-Ontario Drug Benefit marketplace, to charge for the cost component of the**

**prescription price the amount that was actually paid for the product if this amount was less than the best available price.**

**5.1.5.2 Multiple-source Products:** Multiple-source products are those which are sold by more than one manufacturer. Generic product manufacturers will determine which products hold a large enough market share to warrant the investment necessary to market an additional product; they will then attempt to get their generic “copy” of the brand name product approved. This involves approval by the HPB and the determination by the DQTC that the two products are interchangeable.

Multiple source products are marketed quite differently by the brand name manufacturers than are single-source products. The generic manufacturers also employ tactics which differ markedly from those of their brand-name counterparts.

Because the legislation in Ontario requires the pharmacist to dispense the lowest-priced equivalent product to fill so many prescriptions, the point of sale for multiple-source products is generally the pharmacist. Thus the objective of the manufacturer is to influence the pharmacist to buy a particular brand. Economics dictate that the basis for this competition is generally price: pharmacists look to the product which is most profitable. And manufacturers compete on the basis of the lowest price listed in the formulary, for which the pharmacist will be reimbursed when that product is dispensed. The BAP is usually established by one of the generic manufacturers; when the BAP for a particular formulary has been set, other generic manufacturers usually lower their own listed prices to BAP in order to sell their product to the pharmacist. Rarely, in this situation, will the pharmacist purchase a product which is sold at a price higher than BAP.

The brand-name manufacturers usually compete on the basis of factors other than price. The non-formulary market, and the habit of physicians to write “no-substitution” on some prescriptions, enable the pharmacist to purchase and sell the brand-name product. Although non-price competition usually applies to brand-name products, there are notable exceptions. One example is Acetaminophen compound with codeine, 30mg tablet. The price listings in the January 1990 formulary for this multiple-source product were as follows:

Atasol-30	HOR	.0358
Exdol-30	FRS	.0684
Tylenol No.3	MCN	.0368
Lenoltec No. 3	TCH	.0354
Novo-Gesic C-30	NOP	.0365

Following the formulary release, two companies, McNeil (MCN) and Novopharm (NOP), sent letters to the drug programs branch, advising that their BAP was now equivalent to the lowest listed, or .0354. McNeil is considered a brand-name company but it competes—and apparently successfully—on the basis of price. Tylenol No. 3 holds by far the lion’s share of the Acetaminophen plus codeine market, illustrating the ability of this brand-name manufacturer to compete successfully, at least in specified products, on the basis of price.

## 5.2 Hospital Purchasing Plans

Most of the information for the following section was taken from the submissions of the OHA.<sup>56</sup>

Integral to the cost efficiency of the drugs used to treat patients in most hospitals in Ontario is the HPP. As a service to its members, the OHA negotiates the prices of most commonly-needed and used drug products with the manufacturers under this plan.

<sup>56</sup> Ontario Hospital Association Briefs #57-5100 and #57A-5100.



The existence of a limited formulary, and restricted prescribing practices for hospital physicians, controls the number of available drugs within a hospital. This has the effect of both reducing inventory levels and managing the levels of technological expertise required. (In addition to improving the quality of prescribing, it has the effect of removing drugs of less than optimal safety and efficacy.)

“Hospitals acquire drugs primarily by participating in pharmacist-directed group purchasing programs. There are two major Ontario programs: virtually all hospitals outside of Metropolitan Toronto participate in the Hospital Purchasing Program (HPP) of the Ontario Hospital Association, while Hospital Purchasing Incorporated (HPI — a division of Carecor Health Services Incorporated) handles Toronto area facilities. As well, there are a few smaller, regional purchasing groups.

“HPP handles contracts for some 1,100 items, representing various strengths and sizes of approximately 300 therapeutic entities, or approximately 50 per cent of items listed in many hospital formularies.

“The efficacy of group purchasing is widely accepted. For items not covered by group purchasing contracts, hospitals generally deal directly with suppliers to ensure further savings and, as a last resort, may use a more expensive wholesaler.

“Many community hospitals outside major urban centres rely on reciprocal arrangements with local retail pharmacies when purchasing unusual, difficult-to-source items. Choice of suppliers is made based on two primary considerations: quality and cost. Product quality is determined by bioequivalency, product integrity, labelling, packaging and compliance with accepted

standards. Fiscal factors include volume, cost, minimum order quantity, the distance of the hospital from the warehouse and company performance.

“The Hospital Purchasing Program of the Ontario Hospital Association estimates that member hospitals save approximately **\$2 million annually** based on the approximately \$20 million tendered for HPP hospitals.”<sup>57</sup>

The HPP uses a committee made up of hospital pharmacy directors to approve the bid list for each drug product; the criteria include cost and product quality. HPP only negotiates the contract with manufacturers. Members are notified of contracted prices and terms for ordering. The member hospital deals directly with the manufacturer on these terms; it is only when problems arise that HPP will deal with the manufacturer on behalf of the institution.

HPI has 46 member hospitals, and the program controls close to 50 per cent of Metro Toronto’s market for hospital pharmaceutical products. HPI contracts for \$30 million of pharmaceutical purchases.

“Smaller hospitals, particularly those under 100 beds, are faced with unique challenges in the drug acquisition process. Many of them belong to HPP, but because of their size and the small quantities they use, their orders are often under the minimum dollar value required for free shipping. This occurs with direct buying from the manufacturer as well —if the minimum order is \$100 or \$150 and only one or two items are required, a \$10-\$25 processing and shipping fee is charged. This results in the use of a drug wholesaler or a local retail pharmacy at premium prices.

“This is substantiated by information from the Lilly Surveys which indicate that across the

<sup>57</sup> Ibid., #57A-5100, p.47.

country, hospitals with less than 100 beds have the highest inventory per patient day and purchases per patient day costs.”<sup>38</sup>

This latter point arises not just from the increased purchasing costs of smaller hospitals, but also from the decreased effectiveness of the use of the formulary system as a tool for cost and quality control.

“A formulary limits the number of drugs which must be stocked by the hospital and avoids the acquisition of therapeutic duplicates. The drug products included in the formulary are listed generically, and it is the responsibility of the pharmacy department to determine which supplier will be used for each product.

“In addition to optimizing drug therapy, formularies control drug costs by minimizing drug inventories. This is achieved by limiting the number of drugs, dosage forms and strengths stocked and by selecting the most economical product within a particular category...

“Although well-controlled formulary systems are in place in many of Ontario’s medium to large institutions, some smaller hospitals report that their physicians have been allowed to prescribe and obtain whatever they want for their patients, (and) resist any type of control procedure on the grounds that it restricts their right to practice. Even if a small hospital does produce a formulary, doctors may be unwilling to work within that framework. There may therefore be little understanding or support from administration and the pharmacist ends up being the ‘policeman’.”<sup>39</sup>

“The hospital formulary is ‘the foundation of any system to contain drug costs’

(Abramowitz, 1984). Most studies have been directed at controlling antimicrobial use since these drugs account for 19 per cent of total drug budget (Rucker, 1982). Several studies have reported savings ranging from 25-55 per cent using various techniques (Craig et al, 1978 and Kunin et al, 1973). These studies, however, do not appropriately address the impact of deleting the antibiotic from the formulary on actual patient care. For example, no study included patient outcome or other measures of improving rational drug therapy (Craig et al, 1978). In addition, cost-effectiveness studies concerning restrictive formularies found that while drug costs fell, other related costs rose (Hefner, 1979). Therefore control of the costs of drug use by deleting formulary drugs should be implemented carefully, with an awareness of its potential consequences on patient care. It should be viewed as only one way in which drug costs could be controlled (Hoffman, 1984 and Plumridge et al, 1984).

“User acceptance is essential for the implementation of a formulary (Hoffman, 1984; Plumridge et al, 1984; and Harding et al, 1985). Change is more likely achieved when there is continual and active participation from users and when information accompanies the guidelines or formulary (Harding et al, 1985). Simple communication of guidelines has little impact and has resulted in the inappropriate use of the formulary (Plumridge et al, 1984). In contrast, lectures, personal contact, individualized feedback and written material promoting formulary use have been found to be more effective on changing drug use patterns (Check, 1980). This suggests that communication should be personalized rather than dictatorial (Lamay et al, 1981).”<sup>40</sup>

<sup>38</sup> Ibid., #57A-5100, p.49.

<sup>39</sup> Ibid., #57A-5100, pp. 46-47.

<sup>40</sup> Carruthers, G., T. Goldberg, H. Segal and F. Sellers, *Drug Utilization: A Comprehensive Literature Review*, Ont. Ministry of Health, Toronto, Ont., 1987, pp.185-186.

"The basic question remains why even the best formularies still use and/or add drugs whose therapeutic credentials are so inferior. A minor reason for this deviance may be traced to several products for which conflicting opinions on therapeutic merit obtain. Some variance also may emanate from the unique drug requirements of a particular institution or the ascendancy theory mentioned above. Most of the variance, however, probably stems from the random appearance of subjective factors that influence the decision-making process exercised by the pharmacy and therapeutics committee. In the terminology of the respondents, sub-optimal drugs get into the formulary because committee members, from time to time, are swayed by 'political considerations'."<sup>41</sup>

For reasons of good drug therapy and economics, the Inquiry supports the concept of a limited formulary. This concept has been employed successfully in many hospitals across Ontario and we believe it should be expanded and enhanced.

Therefore, the Committee has endorsed (see recommendation 7.12) a limited formulary, implemented province-wide, both in institutions and in community practice.

### 5.3 Third-Party (Private) Insurers

The majority of Ontarians have or can have the costs of their prescriptions covered by private, or third-party, insurers. The various terms and provisions of insurance plans mean that some insured individuals will experience a financial barrier which denies them access to appropriate and needed products; however, that number should be very limited. Insurance plans vary according to the depth of

coverage (the limitation of the financial responsibility the insurer is willing to take and the copayment level required of the insured individual), and the breadth of coverage (the type of product covered by the plan).

A study for the Inquiry conducted by Dr. J. Hurley "An examination of access to prescription drugs in Ontario and an evaluation of selected cost-sharing policies" (see appendices, volume II) examines the range of private insurance coverage for drugs, discusses the adequacy of benefit coverage, and tries to determine the level of population in Ontario which is inadequately served.

Unfortunately the results were estimates rather than concrete numbers; "...to truly measure access requires comparing the distribution of drug needs with the distribution of resources (including third party coverage) to identify segments of the population for which needs exceed resources. The data required for this task, however, are not available."<sup>42</sup> Nonetheless this report will rely heavily on that research, as it is the best available data.

In view of the inability to determine exact access, the best guess usually makes a determination of the proportion of the population which has some form of private insurance. Most people with private coverage have obtained it as an employment benefit, Green Shield has stated that less than 1 per cent of its coverage is for policies bought by individuals.

There are two ways in which a private insurer can control the level of risk that it is exposed to: by controlling the breadth of coverage or by controlling the depth of coverage. Controlling the breadth of coverage will affect the acquisition of specific types of products by the

<sup>41</sup> Rucker, T. Donald, "Superior Hospital Formularies: A Critical Analysis", *Hospital Pharmacy*, 17, 1982, p.465.

<sup>42</sup> Hurley, Jeremiah, "An Examination of access to prescription drugs in Ontario and an evaluation of selected cost-sharing policies" (see appendices.)



people who are insured; controlling the depth of coverage will affect utilization in general. Probably neither will have any appreciable effect on drug prices.

The discussion of depth of coverage is found in the section of chapter 9 dealing with the consumer and access to drug benefit coverage.

Breadth of coverage differs very little between plan types. The two largest of Ontario's private insurers, Blue Cross and Green Shield, have more than one type of plan, but their most "limited" plan covers all basic prescription drugs, while the more "generous" plans will cover special drugs or disease categories, as well as many over-the-counter medications.

Depth of coverage is extremely variable among different plans. Each insured (group or employer) negotiates the benefit levels—in terms of coinsurance, copayments, total annual coverage limits and total lifetime coverage limits—separately with the insurance company.

Because of the record-keeping methods of the insurance companies, only average insurance data is available. For 1988, Blue Cross shows the average cost per prescription to be \$23.13 (as opposed to the average ODB cost of \$18.37). Of this, the covered individuals paid an average of \$1.59, or 7 per cent. The average subscriber paid a total of \$18.91 per year for drugs, which translates to about 11.9 prescriptions per year. In contrast, the ODB average number of prescriptions per year is 23.6.

However, because of a variety of factors, including ignorance of coverage, a number of individuals with private insurance plans will fail to utilize their coverage. In

comparison, the utilization rate under the ODB plan has been extremely high. This rate of utilization, as well as the generally higher level of medication usage of the ODB as a group, explains most of the difference in the numbers of prescriptions per year. But the copayment and limitation of coverage provisions undoubtedly account for some of the difference.

The insurance companies will pass on the risk of increasing annual prescription costs in the premiums charged to the individuals and groups they cover. Actually, the risk of increasing costs is a fairly small element of the drug insurance business, at least for one company: "The revenues of Green Shield are derived approximately 17 per cent from rated or premium groups and about 83 per cent from 'administrative services only' (ASO) groups. A rated group is one which pays monthly rates to Green Shield, based upon single or family coverage, with Green Shield undertaking the risk and establishing reserves for incurred but unreported claims (IBNR). Under the ASO system, Green Shield pays the monthly approved and submitted claims of pharmacists, and invoices the group for the amount of claims paid, plus an administration fee. The group accepts the risk and liability of IBNR claims. (Parenthetically, it might be observed that ASO arrangements are now common in Ontario with large employer groups)."<sup>43</sup>

The result is that the majority of the changes in the average cost of drugs, the cost of pharmacist fees, or the average number of prescriptions per individual, passes on quickly to the employer. The employer then realizes a change in the cost to produce the goods or services sold. The smaller number of rated groups will be slower to feel the impact of changes, but the changes are passed on in the form of premium changes. One of the issues

43 Brief by Green Shield Prepaid Services Inc., #103-3200, p.4.

of concern expressed in the brief by Green Shield is the effect of, and concern with, the increase in prescription costs, and in particular that element of the increase contributed by increasing average drug costs.

“By way of example, one of the significant areas of union negotiations in the automotive industry in the bargaining years 1982, 1984, and 1987 revolved around the issue of control of drug costs, and the selection of the approved level of drug services to be provided. For the employees this was a highly significant issue since it meant that drugs not covered in the approved benefit schedule would be borne solely out of their own pockets...Thus a needed drug, for which no third party coverage is provided, has a direct impact upon the employee measured either by the actual cost coming out of the employee's pocket, or by the employee receiving a less than adequate drug for the sickness involved because the employee cannot afford the high cost of the properly needed drug... In a like manner, the continually increasing drug costs are a cause of great concern to employers. Thus attempts to limit the effect of these increases, either by imposing a portion of the cost upon the employees, or by changing the level of services, becomes a serious matter. (Simply as a matter of example, one employer, in negotiations in 1982, proposed to change the level of benefits provided to its employees by establishing a generic plan, and in making that proposal, anticipated savings of some \$750,000 annually. Extrapolating that amount into the whole Canadian scene indicates the magnitude and the potential for reduction or restraint of costs available to all Canadians).”<sup>44</sup>

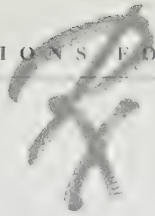
The concern over cost containment has resulted in the promotion of various cost savings measures by Green Shield, the only private insurer to make a submission to the Inquiry. “We perceive a growing economic thrust in promoting product selection because it is clear, in our view, the use of interchangeable drugs, can reduce, or at least restrain the upward rise in drug costs.”<sup>45</sup> The analysis done by the company for 1986, when an estimated \$1.2 billion in third-party (including ODB) claims were paid, indicates that the estimated savings resulting from product selection were \$94.2 million. Because only limited product selection was available, the actual saving was roughly half that.

“It is clear that product selection is a very important element of cost containment. However product selection is unlikely to occur unless there is a mandate which requires the application of product selection... There is much pressure in the marketplace by the pharmaceutical brand name manufacturers against product selection. Since product selection is obviously useful in reducing or restraining costs, we expect that, in the future, more and more plans will be designed to bring about product selection.”<sup>46</sup>

<sup>44</sup> Ibid., #103-5200 p.7-8.

<sup>45</sup> Ibid., #103-5200 p.16.

<sup>46</sup> Ibid., #103-5200 p.19.



## Chapter VI

### Distribution of Drugs

*The distribution of drugs, particularly the role of the wholesaler in a changing marketplace, is examined by the Committee in light of its concern to make drugs universally and economically available. The chapter also examines and makes recommendations with regard to Ontario Government Pharmaceutical and Medical Supply Services and the hospital unit dose system.*

#### 6.1 Role of Wholesale Drug Distributors

The major part of sections 6.1.1, 6.1.2 and 6.1.3 appeared first in the Third Quarterly Report of the Inquiry.

##### 6.1.1. Overview

The wholesale drug distribution system in Ontario is reported to be facing pressing and complex problems. There are conflicting explanations of these difficulties, (primarily a decreasing market share) and, of course, conflicting suggested solutions for their resolution.

We therefore propose to outline briefly our understanding of the current situation and the underlying causes. We will state some basic principles we feel must be protected, identify alternative solutions, discuss briefly our concept of the implications of each of these and finally make recommendations.

##### 6.1.2 Current Situation

The wholesale distribution of drugs in Ontario is performed by the segment of the industry which ensures that drug products are delivered safely and efficiently from the

manufacturer to their destination: the hospital or retail pharmacy. Some manufacturers choose to do this directly; others hire another company to act as agent to deliver drugs for them; yet others choose indirect distribution, selling their products to a company which is in the business of wholesale delivery.

Ontario has three major companies that distribute drug products to retail pharmacies and hospitals. One is a pharmacist-owned cooperative; another acts purely as manufacturers' agent; the third is a subsidiary of a large national conglomerate.

The wholesale distribution of drugs is not as simple as the distribution of most other products: great care must be taken with record-keeping in order that products can be quickly accounted for or traced if a recall occurs and drugs must be safeguarded from theft, diversion and damage. There is a wide range of products, some of which are very costly. To a certain extent, hospital pharmacists can plan and budget closely for prescription medication supplies because the hospital environment deals with a limited formulary and a limited number of prescribers. This is in direct contrast to the community or retail setting, where the sale of prescription medications depends entirely on a demand created by an order from a prescriber. In the interests of patient



treatment, a prompt and efficient delivery system is required. Thus, community pharmacists depend on the wholesaler to enable them to stock or have quick access to a wide variety of products. The wholesaler's ability to respond quickly also allows the pharmacist to take advantage of lower inventory levels.

Historically, wholesalers taking advantage of volume purchasing have warehoused products and then sold them to the retailer. Three factors have affected the relationship between retail pharmacies and wholesalers in recent years. The first has been the advent of large chain and franchise pharmacy operations which has resulted in direct group buying from the manufacturer, by-passing the wholesaler. The second has been the increasing generic competition for pharmaceutical medications. More manufacturers now sell products for which there is more than one brand, which creates a strong incentive to monitor and influence the pharmacist who is making purchasing decisions. Previously, it was only the prescriber (usually the physician) who needed to be influenced.

The third factor has been the 1986 introduction of the concept of best available price (BAP). There is a legislative upcharge<sup>1</sup> (currently set by regulation at 10 per cent) which the pharmacist receives; this is provided whether or not the product is purchased directly from the manufacturer or his agent, or indirectly from a wholesaler. The current legislation<sup>2</sup> does not permit the addition of a wholesaler charge to BAP, and when purchases are made from the wholesaler, the pharmacist does not directly recover the wholesalers' charges. This results in a relative reward for the pharmacists who purchase directly from the manufacturer.

As a result of a combination of these three factors, there is said, in recent years, to have been a shift in the distribution of drugs from indirect to direct; this has resulted in a decrease in the market share held by wholesale distributors. Published data have indicated a major one-year shift in the percentage of manufacturers relying mainly on wholesale distribution to those which conduct mainly direct distribution.<sup>3</sup>

It is important to note that almost all manufacturers of drug products use a mixture of delivery methods; manufacturers who have their own or an agency distribution system also have some products shipped through wholesalers; manufacturers who use wholesalers for the majority of their deliveries will still make some larger shipments directly.

The result of this shift, however, is that the indirect wholesale distribution companies have been losing market share; several have expressed concern about the very viability of their industry in Ontario. However, despite the reported reduction in market share, it would seem that the volume of sales has continued to rise.

### 6.1.3 Principles

Before considering possible solutions to the problems of the wholesale distribution system, it seems worthwhile to consider some principles which, in the view of the Committee, must be protected.

- 1. Prescribed drugs must be made available within a reasonable time to all patients who need them, irrespective of their geographic location within Ontario.** An effective wholesale distribution system would seem to be required to ensure this,

<sup>1</sup> Ontario Drug Benefit Act, R.S.O. 1986, C.27.s. 18(4).

<sup>2</sup> Ibid., s. 18(2).

<sup>3</sup> Between January 1987 and January 1988 there is said to have been a decrease of just over 11% in the market share held by wholesale distributors (from 56.8% to 45.1%). This data was presented to the Inquiry at its public hearings.

in that it is not possible for all pharmacies to stock all approved drug products, nor can all manufacturers assure prompt availability of all products. Further, some manufacturers tend to provide direct distribution only to pharmacies and hospitals in or close to urban areas, relying on wholesale distributors to service the more remote areas of the province.

2. **Whether it is direct or indirect, the manner of distribution of drug products should be revenue-neutral to pharmacists and should be determined by such factors as effectiveness and efficiency of distribution.** Pharmacists should not be motivated by financial incentives in choosing to obtain drug products either from the manufacturer or through a distributor.
3. **The final recommendation should not require additional public funds.** Tax dollars are already in place to support the distribution of drug products in Ontario. Manufacturers who choose to make direct distribution available have included the distribution costs in the BAP to pharmacists. Since 1986 pharmacists have received a 10 per cent add-on to the BAP to compensate for wholesale distribution costs that they incur.
4. **The recommendation to be made should not result in windfall "distribution profits" for drug manufacturers whose profits properly derive from the sale of the products.** As already indicated, manufacturers who have chosen to distribute products directly to pharmacists have built the costs into the BAP.

No additional financial benefits should flow to a manufacturer who makes a decision to distribute directly. A decision by a manufacturer to switch from wholesale to direct distribution (for example, for marketing or promotional purposes) should not be subsidized by the Ontario Drug Benefits (ODB) program.

5. **Distribution costs should be paid to those who incur them.** They should not be used as a "back door" supplementary payment for other services.

#### 6.1.4 Proposed Solutions

Several solutions were proposed and some of those presented for public discussion and response. Options one and two were proposed by the Canadian Wholesale Drug Association; option three was proposed by Green Shield Prepaid Services Inc.; options four and five were independently produced.

1. Revert to the mechanism in place prior to the enactment of the Ontario Drug Benefit Act and the Prescription Drug Cost Regulation Act in December, 1986. This would involve allowing "wholesale oriented manufacturers" (for which a definition was established), to quote the price that they would charge to wholesalers. The Ministry of Health (MOH) would then list a BAP which would include a percentage mark-up to cover the wholesale distribution cost. The pharmacist would be reimbursed at this higher BAP.

This proposal does not involve an adjustment to the 10 per cent currently added to BAP by regulation pursuant to Section 7(3)(b) of the Prescription Drug Cost Regulation Act. However, it would require the infusion of additional public funds.

2. Encourage agency agreements instead of indirect distribution. A manufacturer who now distributes indirectly through a wholesaler sells at BAP to the wholesaler who, in turn, sells the product to the pharmacy at BAP plus the distribution charge. In agency agreements, the manufacturer turns over the product to the agent distributor who sells it to the pharmacy at BAP. The agent distributor receives from the manufacturer a percentage of BAP to cover the distribution charge. In this case,

the pharmacist does not have to pay any additional distribution charge because it is incorporated in the BAP.

This proposal also does not involve an adjustment to the percentage added to BAP by regulation made pursuant to Section 7(3)(b) of the Prescription Drug Cost Regulation Act. However, it too would require the infusion of additional public funds because the BAP for drugs delivered by an agent distributor would be higher.

3. Make an adjustment to the percentage added to BAP that would compensate the wholesale distributor. In this proposal, a base of 6 per cent would be added to BAP for direct purchases from manufacturers of drugs and 14 per cent (6 per cent plus 8 per cent wholesale charge) for products purchased from the wholesaler. The result of this would be that the pharmacist would charge and receive BAP plus 6 per cent for drugs purchased directly from manufacturers. If drugs are purchased from a wholesaler, the pharmacist would charge BAP plus 14 per cent and receive a net of BAP plus 6 per cent (14 per cent–8 per cent wholesale charge). If purchasing continues to be divided approximately evenly (as at present) between wholesale and direct distribution the overall cost to the public would remain at BAP plus 10 per cent.

This proposal does involve a change to the percentage added to BAP by regulation made pursuant to Section 7(3)(b) of the Prescription Drug Cost Regulation Act of Ontario. It should not require more public funds.

4. Vary the reimbursement to the party delivering the product, depending on whether the product is single-source or multi-

source.<sup>4</sup> A manufacturer who delivers a single-source product directly to the pharmacy would get no additional reimbursement. A manufacturer who delivers a multi-source product directly would be reimbursed at cost plus 5 per cent for that delivery. A wholesaler who delivers a single-source product would be reimbursed at 5 per cent over cost, and a wholesaler who delivers a multi-source product would be reimbursed at plus 10 per cent. This proposal would require redefining BAP as a price for the drug alone, not including distribution costs. Every BAP would have to be rolled back by 5 per cent, across-the-board, once.

This proposal does not involve an adjustment to the percentage added to BAP by regulation made pursuant to Section 7(3)(b) of the Prescription Drug Cost Regulation Act. The wholesalers would receive an overall average of about 8 per cent more for drugs distributed indirectly.

5. Recommend that no action be taken by the government, allowing the parties concerned to find their own solution under the influence of market forces.

The Inquiry was not satisfied with any of these proposals, and requested responses from interested parties on the principles and alternative proposals presented in the third quarterly report. A day of open hearings was held on the issues.

### 6.1.5 Issues and Recommendations

Subsequent to the forum, the principal issues and their impact on distribution were clarified. They are as follows:

<sup>4</sup> Because of marketplace competition, multi-source products usually sell at a price considerably lower than single-source products.



**1. The 10 per cent upcharge.** There is no agreement as to the original intent of this charge. Individual pharmacists and the Ontario Pharmacists' Association (OPA) have taken a stance that it is for inventory costs; the MOH and others believe it was designed to cover distribution costs, yet others have regarded it as an administrative allowance. The Canadian Wholesale Drug Manufacturers Association (CWDMA) has stated in its submission to the Inquiry that: "The 10 per cent pharmacy purchasing advantage negotiated by the OPA and provided in the new legislation has nothing to do with the traditional distribution cost allowance (10 per cent). The former is applicable at the retail level for whatever purpose the Ministry had in mind. The latter was previously allowed by the Ministry as an addition to the base price in the formulary, which, in effect, is the price of the product at point of use. Today the pharmacist takes the 10 per cent purchasing advantage as being totally his.

"The Ontario government has agreed to pay the cost of distribution for products sold direct because this cost is already built into the direct manufacturer's [i.e. the manufacturer that sells directly to the retailer] price. However, our Ministry of Health, does not recognize this same charge if delivery of the goods is handled by a wholesaler/distributor."<sup>5</sup>

Edwin Chow of The Village Pharmacy suggested in his submission: "The answer is to provide for a pricing differential between differing sourced products. Since other recommendations in the final report from the Commission may suggest changes to the legislation, it would not be unrealistic to also make changes to correct the definition of BAP to reflect the cost to the dispensing pharmacist and basing BAP on the most common (75 per cent) source of procurement by dispensers, as based on manufacturer's

records. ...I must disagree in the strongest terms with the statement in principle three regarding the 10 per cent add-on to BAP being for the purpose of compensating for whole-sale distribution costs. As previously stated, the add-on is to compensate for higher costs associated with purchase of less than maximum sized containers of product, on which the BAP is usually based."

The first-order effects of the upcharge are clear: There are definite financial incentives for the pharmacist to purchase direct and to have the manufacturer absorb distribution costs. As a result, there has been a marked shift to direct distribution and the market share and profit margins of wholesalers have declined. Drug Trading also stresses that it provides low minimum values for single orders to retail pharmacists. Under the current system, the company charges an 8 per cent wholesale charge to its customers on the invoice. This 8 per cent now becomes a cost which the pharmacist/retailer must try to recoup as it is no longer reimbursable by the government. Drug Trading feels that pharmacists are supportive of the wholesalers' dilemma on the one hand but are also encouraging smaller manufacturers to sell more products directly.<sup>6</sup>

Livingston Pharmaceutical Distribution Ltd. assumed the concept of BAP would remain. Current BAP regulations recognize the reality of distribution. It does not cost the system more to purchase through a wholesaler than to purchase direct. Each level of the distribution chain (change in ownership) adds a cost and a value. The value the wholesaler adds is convenience plus reduced store inventory but at a cost of between 5 and 7 per cent. Livingston suggested that the current 10 per cent add on to BAP be reduced to 7 per cent and noted that manufacturers must be allowed to choose the direct distribution

<sup>5</sup> Brief from CWDMA, #2-3100 pp. 4-5.

<sup>6</sup> Brief by Drug Trading, #31-3200.

channel. This includes adjustment to BAP if the net cost to the dispensing point is less than the current wholesale selling price. A manufacturer chooses to go direct in order to have a shorter distribution chain. The direct channel offers a closer relationship with the dispenser, control of product, price and packaging to the dispenser, and improved product recall capability. Some companies feel that being direct helps meet compulsory licensing and generic competition. The proposed solution was that product reimbursement should be actual acquisition cost (AAC) defined as BAP plus distribution costs up to a maximum of 8 per cent of BAP. Distribution costs could be wholesaler add-on, or 'minimums', or other extras incurred in buying direct.<sup>7</sup>

The CWDMA recommends reinstatement of the previous system and ensuring that the cost of distribution is reimbursed to the pharmacist regardless of the direct or indirect orientation of distribution by the manufacturer, or, alternatively, that distribution agreements between drug wholesalers/distributors and their clients be legitimized. This would necessitate a one-time uncapping of the price increase or BAP concept.<sup>8</sup>

Several companies, including Rhone-Poulenc,<sup>9</sup> Glaxo,<sup>10</sup> Astra Pharma Inc.,<sup>11</sup> Eli Lilly,<sup>12</sup> Ayerst,<sup>13</sup> Boehringer Ingleheim,<sup>14</sup> Pfizer Canada Inc.,<sup>15</sup> and the Pharmaceutical Manufacturers Association of Canada<sup>16</sup> want drug reimbursement based on AAC to the pharmacist plus an up-charge and a dispensing fee. It, of course, is concerned with the encouragement of the use of generic (cheaper) products, which threaten research-

oriented manufacturers. PMAC feels that the legislation has created a pricing system which is open to abuse, without guaranteeing elimination of price spread. The manufacturers believe that AAC is the only effective method of completely eliminating price spreading and avoiding discriminatory disruption to market competition at the retail, wholesale and manufacturer levels.

However, the Inquiry feels that the second-order effects are now becoming evident. Pharmacists' costs of ordering are escalating as they buy from multiple sellers; inventory costs are up because of the increased minimum amounts that must be purchased; wastage due to outdated stock is up; returns are more difficult; and accounting costs have increased. Pharmacists also complain about the manufacturers' drug detailers who check stock and apply pressure to place orders for specific drugs.

In theory, as the cost and inconvenience of direct buying mount, pharmacists should reverse the recent trend and direct orders back to the wholesalers. This is not happening, presumably because of the enticement of the short term 10 per cent "bonus" of direct purchasing. Pharmacists have come to regard the dispensing fee and the 10 per cent as the two recognized sources of income from the ODB program. It is the stance of the profession that the negotiated ODB dispensing fees have not kept pace with operating costs, and it is only the 10 per cent upcharge (combined with increased dispensing fees charged to cash customers and third party insurers) that has enabled them to maintain earnings.

<sup>7</sup> Brief by Livingstone Pharmaceuticals, #164-3200.

<sup>8</sup> Op. cit., CWDMA, brief and presentation in September, 1989.

<sup>9</sup> Brief #24-3200.

<sup>10</sup> Brief #42-3200.

<sup>11</sup> Brief #80-3200.

<sup>12</sup> Brief #111-3200.

<sup>13</sup> Brief #67-3200.

<sup>14</sup> Brief #113-3200.

<sup>15</sup> Brief #146-3200.

<sup>16</sup> Brief #114-3100.

**2. Wholesalers.** At present, all wholesalers in the province must register with the Ontario College of Pharmacists; 40 have done so, and only two of these offer a full range of services. The remainder are limited in terms of both area served and products inventoried, and range down to small wholesalers owned by pharmacists and others with a restricted trading field.

The registration serves as part of a drug control system, permitting notification of wholesalers in the event, for example, of changes in legislation which affect to whom they may sell their products.

Further, all wholesalers and pharmaceutical manufacturers who sell narcotics and other controlled drugs to pharmacists, physicians, hospitals and others eligible to purchase them must register with the federal Bureau of Dangerous Drugs as "licensed dealers."

Wholesalers purchase products from manufacturers, maintain and warehouse inventories, take orders, ship to retailers and maintain accounts receivable. At present, beyond the requirement to register, there are no government regulations regarding their licensure or control. The Inquiry believes that the MOH, the OCP, the CWDMA and the Ontario Hospital Association (OHA) should jointly establish definitions of wholesalers, and the Ministry should establish guidelines which provide certain minimum standards.

Standards required of wholesalers should extend beyond the simple need to register to include a system of regulations or guidelines dealing with maintenance, operation, staffing and service policies. Since this Inquiry is primarily interested in those elements of service that result in the public receiving medication as quickly as possible, we believe that availability of all prescribed products and fast, province-wide distribution should be addressed with priority.

**6.1** The Committee therefore recommends that minimum standards be established for services provided by wholesalers, in order for their charges to qualify for reimbursement as set forth below in recommendation 6.2. These standards should include availability and fast, province-wide distribution of most prescribed products.

**3. Direct selling.** This has become part of the marketing strategy of those manufacturers who attempt to enhance market share through direct contact with pharmacists, by monitoring their drug inventories and taking and influencing orders. While there is every reason to believe the practice will continue to grow in urban areas because of the upcharge incentive, this may not be true of small, rural pharmacies which find it difficult to meet some companies' minimum order requirements and to obtain timely delivery. Agency distribution agreements and drop shipments (described below) should generally improve delivery.

**4. Distribution agreement.** A distribution agreement is an arrangement where the drug manufacturer engages a third party to deliver products to the retailer. The third party agent does not take ownership of the product and may or may not warehouse it and maintain accounts receivable. The agent's remuneration for this service can be either a percentage of the sale price of the product, or a fee paid to the agent by the manufacturer. In either case, BAP has been set to include this agency remuneration.

The MOH questioned the legality of new distribution agreements between manufacturers and wholesalers (which would involve a price increase which would include an amount for agent remuneration) on the basis that these constitute tacit recognition that the price paid by pharmacists includes distribution costs and does not represent the true BAP envisioned by the Prescription Drug Cost Regulation Act.



The wholesalers disagree with this position, but have not entered into distribution agreements.

**5. Drop shipment.** In a drop shipment, the manufacturer ships directly to the pharmacist and pays the wholesaler a fee— usually 2 to 4 per cent of the sale— for billing and collecting payment. Drop shipment agreements do appear to challenge the concept of BAP. The fee is absorbed by the manufacturer and the pharmacist pays BAP without any additional charges for shipping or accounting.

Various proposed solutions to the wholesale distribution problem, which were set forth in the previous interim report and discussed at a subsequent open forum, have now been rejected by the Committee as being unworkable or inappropriate.

Taking into consideration all the views made known to us, the Inquiry has arrived at a set of recommendations which we believe will protect the public interest in the drug distribution process.

**6.2** The Committee therefore recommends that, immediately upon consideration of these recommendations, the Ministry of Health permit wholesalers to enter into agency distribution agreements with manufacturers.

**6.3** The Committee further recommends that, to coincide with the effective date of the current renegotiation of the pharmacists' fee, the Ministry of Health take appropriate steps to reduce the percentage added to the best available price to a level designed to compensate for the actual amount the pharmacist must pay to the wholesaler, and to eliminate entirely the upcharge added to BAP for direct sales.

This recommendation would make the decision regarding the mode of delivery revenue neutral to the pharmacist and would help create a "level playing field" for wholesale distributors. Since the surcharge would no longer be a significant source of revenue for the pharmacist, the professional dispensing fee would have to be adjusted accordingly (see recommendation 6.5.)

Overall, this proposal should not result in a net decrease in costs to the ODB, because the savings realized by the decreased upcharge payable for distribution should be added to the dispensing fee to fairly compensate pharmacists for their professional activities.

A decision to promote direct sales, as well as to switch from indirect to direct sales, can be viewed as part of the marketing strategy of a firm. Therefore any associated increase in distribution costs should be paid by the drug manufacturer, and not result in an increase in the listed BAP.

**6.4** The Committee therefore recommends that the Ministry of Health take appropriate steps to ensure that no increase in the best available price is allowed when a drug manufacturer moves from indirect to direct sales.

Negotiations regarding the dispensing fee should take into consideration both the recommendations in this report, which will result in an appropriately expanded professional role for pharmacists, as well as changes in the surcharge proposed in recommendation 6.3.

**6.5** The Committee therefore recommends that, as part of the current dispensing fee negotiation, the Ministry of Health renegotiate the fee structure by which pharmacists are reimbursed to reflect the reduced upcharge and the expanded professional role for pharmacists.

## 6.2. Ontario Government Pharmacy and Medical Supply Services

Ontario Government Pharmacy and Medical Supply Services (OGPMSS), or Government Pharmacy, grew out of a recommendation, in 1960, by the Select Committee of the Ontario Legislature on the Cost of Drugs, to implement a program of central buying and testing of drugs. This committee believed that a centralized pharmacy warehouse would result in a smoother flow of drugs to the testing lab and that centralized buying and warehousing would reduce costs to, and waste by, the hospitals concerned.

Government Pharmacy was established in 1969 when the MOH was appointed the "sole agency for the purchase and supply of drugs, pharmaceuticals and biologicals for human use for the government of Ontario."<sup>17</sup> The stated purpose of the program is to "...procure, warehouse and distribute, in the most economical and efficient manner, drug, pharmaceutical, biological, medical and laboratory supplies for use in Ontario government agencies and facilities, and in public health programs across the province."<sup>18</sup>

At this time, the Government Pharmacy acquires products for all MOH psychiatric hospitals, including mental retardation

centres, provincial labs, jails and correctional centres. On request it will also act for homes for the aged, public hospitals, nursing homes and other agencies. Currently the major psychiatric hospitals have their own clinical pharmacists, but many of the other institutions and agencies have only nursing staff who rely on the Government Pharmacy for these services.

The Inquiry heard both criticism and praise with respect to the services provided by Government Pharmacy. Long-term care facilities in particular expressed a relative degree of satisfaction, but most submissions to the Inquiry were distinctly critical.<sup>19</sup> The Committee has carefully examined the positive and negative comments made during the public hearings, and in written submissions. We also considered the rationale for a centralized pharmacy run by the provincial government, examined both the development of this program over the past 20 years and alternatives. The following is a brief summary and evaluation of the information obtained by the Committee.

The services provided by Government Pharmacy can be evaluated in terms of the five principles set out above for solutions to the wholesale distribution issue. The Inquiry has learned that while Government Pharmacy

<sup>17</sup> Government of Ontario. Order-in-Council, April, 1969.

<sup>18</sup> Ontario Ministry of Health. Government Pharmacy and Medical Stores Manual of Corporate Policy and Procedure #3-675, May 1980.

<sup>19</sup> Among the comments are the following: The Canadian Society of Hospital Pharmacists (Ontario Branch) discusses problems occurring with the system including slow turn-around time, back-orders, and short-dated stock, resulting in excessive returns or wastage. The OB-CSHP recommends that provincially-operated hospitals and long-term care facilities could benefit and accrue significant savings if they were permitted to purchase drugs directly from the manufacturers or participate in group purchasing programs.

The Association of Chief Pharmacists of Ontario Psychiatric Hospitals states that there has been a long history of service level problems; the normal delivery time is four to six weeks. The quality control of the service is also very low; there have been shipments where the expiry date of the product is imminent, poor packaging, and high delivery costs. The documentation also shows that product costs are higher on average than if the product had been purchased through the Hospital Purchasing Program of the OHA. It has been estimated that in 1983-84 savings of \$150,000 would have resulted from just these product costs alone. (It should be noted that some of this saving would have to be spent in OHA fees.)

The Ontario Pharmacists' Association says that public, as opposed to provincially-run, hospitals rarely use Government Pharmacy, even though they have the option of doing so. This is because brands of medications are often distributed to long-term care facilities from Central Pharmacy, and there is wastage of these drugs, because some of them are outdated before they can be used. "Moreover, different formulations are provided from time to time creating confusion among the facility's staff, pharmacists and residents." Finally, the service levels are poor, and brands of drugs which have not been designated as interchangeable are provided.

The OHA says that Government Pharmacy causes major difficulties to OHA members and to provincially-owned psychiatric hospitals and long-term care facilities which are required to purchase all their pharmaceuticals from the Central Pharmacy. The problems with Government Pharmacy include slow turnaround time, back orders lasting seven to 10 weeks and short-dated stock. "OHA believes that significant savings would accrue if these hospitals were allowed to purchase directly, or participate in the independent purchasing programs described above."

Finally, the Ontario Nursing Home Association says that Central Pharmacy requires a different ordering and administration system from formulary medications. Unlike local pharmacies, it also does not supply medications in individually prepared packages. It is inefficient: turn-around for orders is between three weeks and three months, and back orders are slow. Substituted products are often supplied for the physician's originally prescribed product as well.

makes prescribed drugs available to all clients in Ontario, this does not happen within a "reasonable time." For example, pharmacists in psychiatric hospitals served by Government Pharmacy have had considerable difficulty with unpredictable delivery dates and the receipt of drugs unacceptably close to expiry date. Such problems have been less severe for nursing homes and homes for the aged.

The manner of drug distribution, where products are supplied in bulk to the client, is tailored more for psychiatric hospitals and other agencies which employ pharmacists, than for institutions which rely on community pharmacists. Pharmacists who provide services for nursing homes and homes for the aged on a contractual basis are expected to provide value-added counselling services for the over-the-counter products purchased from Government Pharmacy, along with the prescription drugs that they sell and dispense. Community pharmacists provide their clients with complete patient medication records, and drug interaction evaluation based on those records, and must include those products that are prescribed to the patient and obtained from Government Pharmacy, even though the counselling services they provide for drugs they don't sell are costs they have to absorb. Furthermore, the nursing staff in those facilities are expected to dispense the bulk medication in individual doses, while the products they obtain from community pharmacists are usually packaged in unit doses for ease of distribution.

Some Government Pharmacy clients report that it takes two to three weeks for orders to be processed and delivered. This would be acceptable performance were it not for associated complaints: items back-ordered and not sent; time for delivery ranging from one to four weeks, complicated inventory and purchasing control; products received which are unacceptably close to expiry date; delivery charges by third-party carriers, particularly to remote areas; switches in drug products,

package sizes and formats arising from changes in suppliers; and difficulties in returning excess, expired or faulty products for credit.

Such problems appear to be greater for the provincial psychiatric hospitals, which at present must rely on Government Pharmacy for all services, than for homes for the aged and nursing homes, which are required to purchase only over-the-counter products from Government Pharmacy and may purchase prescription drugs from community pharmacists.

The service does not appear to be sensitive to customer complaints and clients report that their concerns are largely ignored. Although a user committee was struck during 1980 to provide a forum to discuss Government Pharmacy service problems, it has not met since 1987. The Inquiry has been told that future meetings are planned.

In addition, the current information management system of OGPMS is not set up to track performance information such as back orders, shipment times, delivery costs and product expiry dates, although the capability to do so exists.

Beyond the stated purpose of Government Pharmacy to procure, warehouse and distribute, it is also charged with testing and evaluating drug products at the Ministry laboratory. According to the latest catalogue, approximately 130 non-prescription drugs, 311 prescription drugs and 33 vaccines are carried by Government Pharmacy and an additional 734 medical and emergency supplies are listed. OGPMS is also required to maintain Ontario's provincial holding of the national stockpile of emergency health supplies.

All requisitions received by Government Pharmacy are reviewed by a staff pharmacist for safety and efficacy. This seems to be an unnecessary duplication of effort; if a product



has been passed and tested by the Drug Quality and Therapeutics Committee (DQTC) and has been, or will be, prescribed by an institutional prescriber, the additional examination of the product by a pharmacist seems unnecessary.

The criteria applied to purchases made for persons covered by the ODB formulary are not applied to purchases made for others. Therefore, ODB standards do not apply to patients who are going to receive Government Pharmacy products unless they are ODB recipients. This results in the inequitable application of the standards and safeguards which have been set up and applied by the DQTC. If the ordered product is not found in the formulary, the safeguards and standards otherwise required of products have not (yet) been met, and the product should not be available for persons whose drugs are being paid for by the government of Ontario.

In accordance with the current rules, the provincial psychiatric hospitals pay the cost of their Government Pharmacy supplied drugs and deliveries out of their budgets; the ODB pays directly for those of nursing homes and homes for the aged. Non-prescription drugs on the approved list are issued without charge to nursing homes and homes for the aged, and the costs of these are charged back to the ODB budget.

Drug products listed in the ODB formulary/comparative drug index and supplied to nursing homes, homes for the aged and homes for special care, are not eligible for reimbursement through a community pharmacy without emergency authorization by the MOH. This authorization will generally only occur when products are out of stock at Government Pharmacy or a delivered substitute was rejected by the ordering physician. This leaves a problem for the ordering facilities if, through oversight or lack of foreknowledge, they have failed to order a needed product, or if the Government Pharmacy delivery is too late for their need.

While Government Pharmacy operations are computerized, it is not yet possible to place orders electronically, although this capability is under consideration.

Overall Government Pharmacy sales for 1989/90 are estimated at \$38.4 million. Of this total, drug products account for \$10 million, vaccines for \$22.2 million and supplies and services for the remaining \$6.2 million.

The MOH has provided figures to show that Government Pharmacy is able to purchase drug products at favourable prices. It is claimed that wholesale prices at BAP would be considerably (45 per cent) above those of Government Pharmacy, while retail costs would be substantially (223 per cent) higher. However, the Inquiry has concluded that these comparisons are valid only for worst-case scenarios. An MOH analysis of unit price and total purchase price for similar products shows that the total value of products priced through Government Pharmacy is 96 per cent of the cost of the same products through Hospital Purchasing Plan (HPP), the purchasing group of Ontario hospitals outside Metro Toronto.

This leads to the conclusion that the Government Pharmacy and HPP prices are approximately equal, making it reasonable for provincial psychiatric hospitals, nursing homes, homes for the aged and other clients of Government Pharmacy to explore other bulk purchasing arrangements. A submission of the OHA also confirms that purchasing through suppliers other than Government Pharmacy need not necessarily result in increased costs.

If over-the-counter drugs were purchased through wholesalers and retail pharmacists, the cost could be greater but would include desirable value added services which should save institutional labour and result in increased quality of care. A recommendation that Government Pharmacy divest itself of the purchase and delivery of pharmaceuticals

should not result in “windfall distribution profits” for pharmacists.

A number of possible solutions to problems with the Government Pharmacy services were proposed in the submissions to the Inquiry.

These included:

- that hospitals (including provincial psychiatric institutions) and long term care facilities be permitted to purchase directly from manufacturers or to participate in purchasing groups;
- that, with the elimination of its warehousing and distribution functions, Government Pharmacy could itself act as a group purchasing program; and
- that provincial psychiatric hospitals and long-term care facilities form and manage individual buying groups.

Combining the comments contained in briefs and submissions with its own research, the Inquiry has concluded that: Government Pharmacy currently offers a limited range of drug products to psychiatric hospitals, homes for the aged, nursing homes and other facilities; there are many justified complaints about the service provided; centralized buying as an effective means to reduce drug costs has been established by other drug purchasing programs, and Government Pharmacy does not provide significantly lower prices; and significant quantities of outdated medication are being disposed of, constituting waste that could be prevented by more efficient distribution techniques.

On the basis of available information, the Inquiry strongly believes that the provincial psychiatric hospitals should be permitted to acquire drug products through existing hospital group purchasing plans.

**6.6 The Committee therefore recommends that, by the end of 1992, provincial psychiatric hospitals be allowed to utilize**

**the Ontario Hospital Association’s group purchasing plan.**

In addition, the Ministry of Health should encourage long-term care facilities to investigate consolidating their purchasing requirements and establishing their own group buying services. Details of alternative methods for provision of purchasing services could be addressed by a comprehensive audit and review of the purchasing, warehousing and distribution functions of OGPMS by the MOH.

**6.7 The Committee therefore recommends that an outside group of consultants be engaged to conduct a comprehensive management and operational audit of the services provided by Government Pharmacy with the express purpose of:**

- a) examining the possibility of the Ministry of Health divesting itself of the purchasing, warehousing and distribution of pharmaceutical products being carried on through either Government Pharmacy or the supply and services branch, in order that these functions be handled through private sector services which now exist or may be developed; or
- b) examining the possibility of developing a more efficient operation of the existing system; and
- c) developing, with the involvement of the organizations themselves, more efficient alternatives to those services currently provided to long-term care facilities; and
- d) examining the establishment of an outside board of directors from the private sector to oversee the operation should it be retained in some form.

Since the Inquiry’s mandate does not cover review of the provisions of biologicals, it is suggested that the OGPMS’ responsibilities for the provision of emergency supplies and biologicals be reviewed separately.

## 6.3 Hospital Unit Dose

"Institutional drug use is currently more than a \$200 million annual expense or one sixth of the \$1.2 billion Ontario prescription drug market. Pharmaceutical supplies account for approximately 3.5 per cent of the average hospital budget. This share may slowly increase as drug costs have been rising approximately 15 per cent a year since 1977."<sup>20</sup>

A survey, conducted by the OHA on behalf of the Inquiry, determined that OHA member hospitals utilized distribution systems according to the following:<sup>21</sup>

	No.	%
Ward stock only	15	8.6
Traditional (nursing)	76	43.7
Traditional (cart)	51	29.3
Traditional & unit dose	32	18.4
Unit dose (oral, IV or both)	32	18.4

In the ward stock system, each hospital ward maintains a stock of most of the drugs required for the patients on that ward. Drug orders are given by the physician and carried out by the nursing staff which will dispense from the drugs stocked on the ward. This involves no pharmacy input at the dispensing level, and the distribution system involves pharmacy only at the levels of ordering and distributing to the wards. Pharmacy checks and balances, and controls over drug interactions and patient profile monitoring, are not easy under this system. A modified version of the ward stock system involves having a pharmacist on the wards to assist with dispensing, drug therapy assessment and drug inventory monitoring.

Traditional dispensing involves greater controls through the involvement of the pharmacy. Medication orders, or prescriptions, are dispensed using a system very similar to that of community pharmacy; the pharmacist reviews the patient medication profile, dispenses small vials of the ordered product to the ward, and checks on required changes. This still involves administration from the vials by the nursing staff.

The more recent methods of hospital distribution systems are the various types of unit dose system. Unit dose pharmacy dispensing involves preparation of the medication order, up until the final form which is a single day's supply of the administrable dose, in the pharmacy. It is only the single day's doses which leave the pharmacy to be administered by the nursing staff. There are both advantages and disadvantages: pharmacy costs for both labour and start-up, as well as capital costs, are higher in the unit dose system. Inventory levels are higher in ward stock and traditional systems. Controls are better in unit dose systems, and there is a resultant saving in nursing time: "...an additional 8 per cent of nursing time becomes available for direct patient care when computerized unit-dose drug distribution systems are introduced."<sup>22</sup> This, of course, is an advantage when there is a shortage of nurses; however, more pharmacy personnel are required and there is also a shortage of this professional resource.

Not all hospitals can benefit from unit dose systems, and the system can be applied to specific areas of the medication dispensing system. For example, it is probably advantageous to install a unit dose intravenous additive system in even small hospitals because of the requirements for specialized

<sup>20</sup> OHA brief to the Inquiry #57-3100, p.1 of introduction.

<sup>21</sup> Most of the information for this section has been taken from the OHA brief, which discusses, among other topics, the different types of hospital distribution systems.

<sup>22</sup> Ibid., p.4.



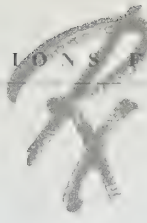
knowledge and aseptic techniques. Wastage in IV systems are cited as one of the main reasons to institute unit dose: "In particular, IV drug therapy has a potential to result in 15 per cent - 30 per cent waste, which amounts to \$100,000 - \$200,000 annually even for a smaller facility (200 beds with \$1 million in drug usage). The literature describes 6 per cent—8 per cent waste in a pharmacy-based centralized intravenous admixture service."<sup>23</sup> But the high initial costs of setting up a unit dose system, combined with the requirements of trained pharmacy personnel, mean that generalized unit dose systems may not be cost-effective for smaller hospitals.

**6.8 The Committee therefore recommends that unit dose/IV admixture programs be identified as the system of choice for institutional drug delivery in hospitals above a certain size.**

**6.9 The Committee further recommends that by 1991 the Ontario Ministry of Health and the Ontario Hospital Association determine the size and other relevant requirements, and that those hospitals identified receive funding for the conversion to a unit dose system.**

---

<sup>23</sup> OHA brief #57B-3100, p.39.



## Chapter VII

### The Prescribing of Drugs

*Despite the general high quality of pharmacotherapy in Ontario, we believe there is considerable potential for improvement. In this chapter we consider the prescribing of drugs, the key role of physicians as prescribers, the education of physicians for this role and, in some detail, ways in which prescribing in Ontario can be improved.*

#### 7.1 Role of the Prescriber

The appropriate prescribing of drug products is an essential component of optimal drug therapy as outlined in chapter 2. Proper use of drugs is an integral part of the medical revolution that Ontarians now take for granted. The benefits of drug treatment are obvious, but all medical treatments, however effective, carry risks. Excellent prescribing, leading to optimal drug therapy, maximizes benefit and minimizes risk. The crucial importance of the concepts underlying rational prescribing were stressed in the submissions to the Inquiry from many organizations.<sup>1</sup>

As these quotations demonstrate, the issues are not new:

*"First do no harm. It is a good remedy sometimes to use nothing."*  
HIPPOCRATES, 460-355 B.C.

*"All things are poisons and there is nothing that is harmless; the dose alone decides that something is no poison."*  
PARACELSUS, 1493-1541.

*"Poisons in small doses are the best medicines; and useful medicines in too large doses are poisonous."* WILLIAM WITHERING, 1789.

*"I do not want two diseases—one nature-made, one doctor-made."*  
NAPOLEON BONAPARTE, 1820.

*"But know also, man has an inborn craving for medicine...the desire to take medicine is one feature which distinguishes man, the animal, from his fellow creatures. It is really one of the most serious difficulties with which we have to contend...the doctor's visit is not thought to be complete without a prescription."*  
WILLIAM OSLER, 1894.

*"Patients may recover in spite of drugs or because of them."* J.H. GADDUM, 1959.

Since the earliest recorded time, mankind has resorted to chemicals (e.g. poppy heads have been found in Stone Age rubble heaps); the use of medication goes back to the origins of medicine. Through history there have been close links between physicians and "physik" (drugs), between medicine and medicines. The tremendous advances in medical treatment parallel, and are part of, the

<sup>1</sup> College of Family Physicians, OMA, Medical Reform Group, Council of Ontario Faculties of Medicine, Association of Jewish Seniors.

technological revolution in the care of the patient that is integral to modern civilization. It is not surprising that over the years society has developed unreasonable expectations concerning medical treatment to the point where, for example, many people now believe all infections to be curable. Every breakthrough in disease treatment reinforces the false expectation that there is “a pill for every ill.”

Cultural expectations vary greatly from community to community, but the issuing of a prescription is expected by many as an essential part of the healing transaction. Because drug therapy aims at changing very complex biological processes, and our knowledge of human biology is less than perfect, adverse drug effects are inevitable. Indeed, even placebos can have side effects. Moreover, drug treatment of symptoms without proper diagnosis can lead to serious diseases remaining unrecognized and therefore untreated.

Physicians play the central role in the medication scenario. In Ontario more than 19,000 of them wrote prescriptions in 1987. Issuing a prescription for a drug product frequently represents the doctor's major therapeutic act. However, this must not obscure the fact that attention, caring, personal engagement, and empathy are essential ingredients of the treatment process; the most important “prescription” a doctor—or other concerned professional such as a nurse or pharmacist—can give is often herself or himself. Genuine human involvement is essential to the healing art; it does not conflict with the science, including pharmacotherapy, but supplements it.

In its submission, the Medical Reform Group made the point that: “Prescribing is an essential feature of the work of almost every

physician engaged in clinical practice. However, despite the central role that prescribing plays in medical practice there has been no systematic exploration of this topic in Canada.”<sup>2</sup> The submission also emphasizes the acute need for additional research of all aspects of prescribing.

While prescribers are educated to first consider the needs of the patient, they also vitally influence the other participants. Without prescriptions, the drug manufacturers' product is not used; the pharmacist has little to do. Positively influencing prescribing behaviour thus becomes essential to the economic well-being of both drug manufacturers and pharmacists. Since the provincial government, or insurance companies on behalf of employers, are now fiscally responsible for part or all of the cost of 85 per cent of the prescriptions dispensed in Ontario, their interest in the cost of prescribing has intensified. Attention to the “cost” component is vital in Ontario; we have already reported that during the past decade the cost of the drug program in Ontario has gone up by 500 per cent (see chapter 3).

Because of the central role of the prescriber, it is necessary to examine the seemingly simple matter of prescription writing in considerable detail, starting with a theoretical discussion and followed by some practical considerations as they apply in Ontario.

Definitions may be dull, but in the context of optimal prescribing a clear understanding of the meaning of the words used is crucial.

**A drug** has been defined by a World Health Organization scientific group as “any substance or product that is used, or intended to be used, to modify or explore physiological systems or pathological states for the benefit of the recipient.”<sup>3</sup>

<sup>2</sup> Brief #40-3500.

<sup>3</sup> World Health Organization, technical report #541:7, 1966.



A drug is a single chemical substance that forms the active ingredient of a drug product which is a particular preparation of one or more drugs. The term drug product can be used interchangeably with medicine or medication. In contemporary society, the word “drug” has sometimes come to mean only a harmful, dangerous, addictive or illicit substance, but this is an abuse of the word. In this report “prescription drug” or “drug” refers to a drug product that is legally made available to a consumer for his or her benefit.

A **prescription** is defined in the Concise Oxford Dictionary as “physician’s direction for composition and use of medicine.” The Health Disciplines Act<sup>4</sup> of Ontario, defines a prescription as “A direction from a prescriber directing the dispensing of any drug or mixture of drugs for a designated person or animal.”

**Prescribers** in Ontario are overwhelmingly physicians. Although dentists also prescribe, we have not specifically examined the use of drugs in dentistry. Dentists account for a very small proportion of the drugs dispensed in Ontario—roughly 4 per cent<sup>5</sup>—and we believe our general approach also applies to dental prescribing.

There is much more to treatment than just prescribing. We found it useful to ask the questions:

**What can the individual consumer reasonably expect of the prescribing physician in the 1990’s?** The answer may be summarized as “optimal pharmacotherapy,” which implies the very **best available** drug treatment, not necessarily meaning the **most expensive**.

A system of optimal pharmacotherapy will, with much overlap, include: accurate diagnosis; informed consent to treatment (and

to the cost thereof); optimal prescribing/rational pharmacotherapy; patient education; and appropriate follow-up.

**What can society as a whole reasonably expect of the prescribing physicians in the 1990’s?** In addition to meeting the above individual patient expectations, physicians can be expected to: evaluate the effects of drugs prescribed, including adverse drug reporting, post-marketing surveillance, clinical trials, and drug utilization reviews; be aware of cost issues and of the appropriate use of generic products; and be appropriately educated for optimal prescribing; this, of course, includes keeping up to date.

**Diagnosis:** Rational pharmacotherapy depends upon accurate diagnosis. Quite often a working diagnosis is all that can be achieved when treatment is urgently needed. Patients are examined, tests are taken, and treatment is initiated on the basis of the best available information. Treatment is later modified as new information becomes available.

In general, both patient and society gain when treatment is delayed until a full assessment of the patient is completed. Clearly, in urgent situations, this is not possible. “Absolute certainty in diagnosis is unattainable, no matter how much information we gather, how many observations we make, or how many tests we perform. A diagnosis is a hypothesis about the nature of a patient’s illness, one that is derived from observations by the use of inference....Our task is not to attain certainty, but rather to reduce the level of diagnostic uncertainty enough to make optimal therapeutic decisions.

“How should we handle uncertainty? To a large degree, the level of diagnostic certainty needed in decision making is a function of the

<sup>4</sup> Health Disciplines Act, R.S.O. 1980, Part VI.

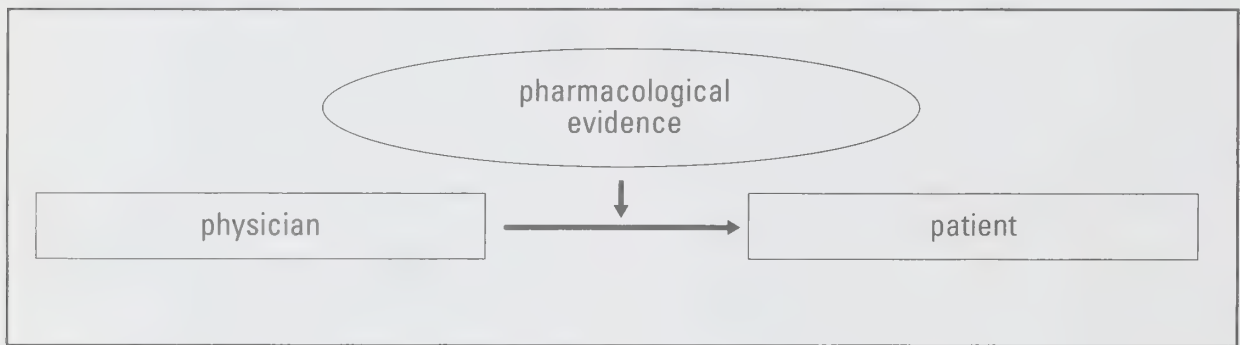
<sup>5</sup> Compiled from informal survey data received from the Ontario Dental Association.

characteristics of available therapies. When a specific therapy is high in effectiveness and low in risk, one can tolerate substantial diagnostic uncertainty (and therefore avoid having to carry out many tests)—not only because the treatment cures the disease, but also because it will cause little harm to patients who do not have the disease. By contrast, any therapy that is not highly effective or that produces considerable morbidity must be given only when the level of diagnostic uncertainty is minimal.”<sup>6</sup>

**A rational and actual information model:** Information models which illustrate factors affecting physician’s decisions may help in considering the problems faced by prescribers.

S.B. Soumerai of Harvard University uses two models. Figure 7.1 depicts an extremely simplistic and idealistic model of physician behaviour; however many medical schools may not go beyond this rational cognitive model.

Figure 7.1 The Rational Information Model



Patients should expect no drug prescriptions, or only minimal short term symptomatic treatment for relatively minor problems, (e.g. insomnia, musculoskeletal aches and pains). Treatment of symptoms without diagnosis can lead to serious diseases—such as depression—remaining unrecognized. Symptomatic treatment should not be considered trivial; on occasion it can also set the ground for tragedy. For instance, an elderly patient may become critically ill following drug induced gastrointestinal bleeding after an anti-inflammatory drug (NSAID) is taken to alleviate joint discomfort and stiffness. The pain and stiffness might have been helped by simple physical methods, or by acetaminophen, rather than a more potent but more dangerous drug. The individual physician’s role is to practice rational pharmacotherapy and to prescribe optimally.

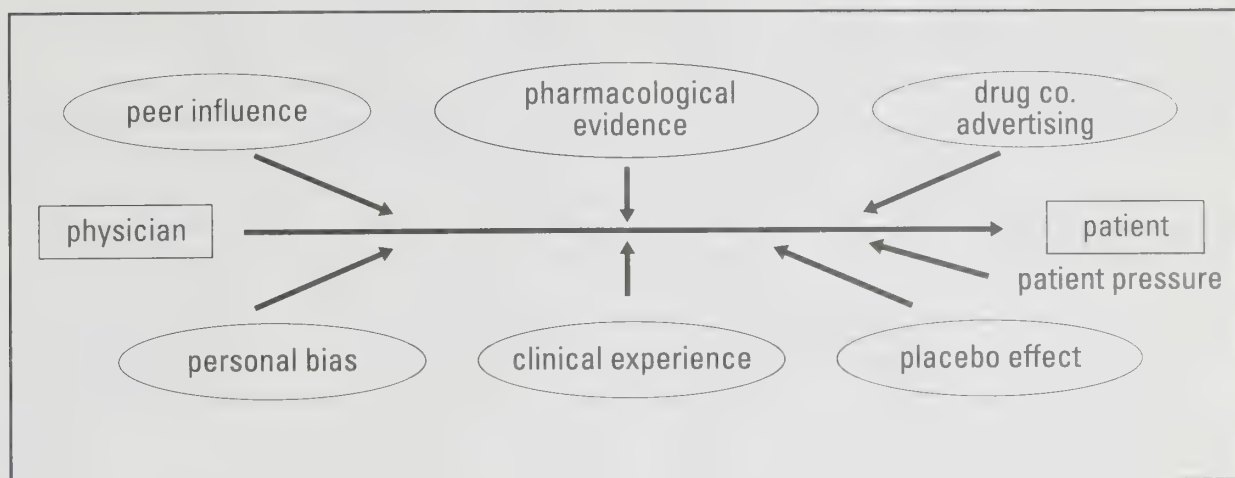
Figure 7.2 is closer to the mark yet it is probably also too simplistic. We would suggest including the influence of education concerning drug evaluation. The concept of rational drug therapy is not new, but is much easier to advocate than to achieve.<sup>7</sup>

Rational pharmacotherapy implies that before treating any patients with drugs, physicians should have made up their minds on eight points: 1) Whether any intervention at all is necessary and if so; 2) What alteration in the patient’s condition they hope to achieve; 3) That the drug they intend to prescribe is best capable of bringing this about; 4) How they will know when it has been brought about; 5) That they can administer the drug in such a way that the right concentration will be attained in the right place at the right time and for the right duration; 6) What other

<sup>6</sup> Kassirer, Jerome P., “Our Stubborn Quest for Diagnostic Certainty: A Cause of Excessive Testing,” *The New England Journal of Medicine*, Vol. 320, No.22 June 1, 1989, p.1489.

<sup>7</sup> Rucker, T.D. & J.A. Visconti, “Relative Drug Safety & Efficacy: Any Help for the Practitioner?” *AM. J. Hosp. Pharm.* 36: pp. 1099-1101, (1979.)

Figure 7.2 The Actual Model



effects the drug may have and whether these may be harmful; 7) How they will decide to stop the drug; and 8) Whether the likelihood of benefit, and its importance, outweighs the likelihood of damage, and its importance, (i.e. to consider benefit versus risk).

It is obvious that drug therapy involves a great deal more than matching the name of the drug to the name of the disease; it requires knowledge, judgement, skill and wisdom, but above all a sense of responsibility.<sup>8</sup>

The necessary skill and wisdom are the products of the prescriber's education, experience and personal innate and acquired capacity. Actual prescribing will fall short of this ideal, but it remains one towards which prescribers should aspire. The treatment strategy must be one which, on balance, bears a reasonable cost.

**Cost implications of rational pharmacotherapy:** As we have seen, a system of rational pharmacotherapy obtains for the patient the maximum benefit for the least possible risk. Rational pharmacotherapy does not, in theory, necessarily consider cost.

However, in practical terms, unless a treatment is affordable by either the patient or his agent (insurer or the state) compliance will be low. At the same time, it does not follow that the most expensive line of treatment is necessarily the best, even if the cost aspect is disregarded in defining "best."

Generally, parsimonious prescribing is good prescribing. Rational pharmacotherapy reduces the potential for adverse drug reactions and interactions to the irreducible minimum. Rational pharmacotherapy is one aspect of optimal therapy and is an essential ingredient in reaching this goal. Unfortunately, rational prescribing cannot be defined universally, or simply, because what is "rational" is determined by many factors. There are considerable differences in what is reasonable to the patient, physician, insurer, politician, or administrator. As already suggested, rational prescribing can be pointless if patient compliance is not high. Patient compliance is affected by health beliefs and behaviours, disease and drug costs, and the attitudes of those caring for the patient. The prescriber must be sensitive to all these issues.

<sup>8</sup> Slightly modified from *Clinical Pharmacology*, by D.R. Laurence & P.N. Bennett (eds.), Sixth Edition, published by Churchill Livingstone, 1987.



**7.1 The Committee therefore recommends that, as an integral part of optimal therapy, rational pharmacotherapy should be the goal for all concerned with the use of prescription drugs in Ontario.**

A centre for the study and promotion of rational drug prescribing has been proposed at McMaster University by its Dean, Dr. S.M. MacLeod (submission January 29, 1990). "Such a centre would include either under one roof, or in a network arrangement, a variety of disciplines which could contribute in one way or another to improve drug prescribing." We believe that such a centre is long overdue in Canada.

**7.2 The Committee therefore recommends that the Ministry of Health invite the pharmaceutical industry to jointly investigate the possibility of shared funding for an Ontario centre for the study of drug prescribing. It would be attached to one health science centre, with linkages to practising physicians through the Royal College of Physicians and Surgeons of Canada, the College of Family Practice of Canada and the Ontario Medical Association, and to departments of clinical pharmacology that, we believe, should be established in each Ontario faculty of medicine (see recommendation 7.17.)**

### **7.1.1 Informed Consent for Treatment - The Drug Information Dilemma**

To some extent, consent for treatment is implied in the usual treatment context when a patient comes to the physician for help with a problem. The power for good is inextricably bound up with the risk of harm. It is generally agreed that: "Informed consent for treatment is a sine qua non of ethical therapeutics but how much information is enough to make sure that consent is informed? Excessive zeal in warning of unpleasant or potentially

dangerous unwanted effects can lead to rejection by patients of essential treatment (by, for example, a severely depressed patient who is apprehensive about the possible adverse effects of anti-depressants.) Increasing numbers of informed patients are aware of the simple but useful concept of the risk/benefit ratio and understand that there is potential risk associated with many ordinary daily activities. Clearly, any drug powerful enough to require a prescription and to produce therapeutic benefit has a potential for harm. Many unwanted effects of drug products are the inevitable and predictable pharmacological response to sufficient medication to achieve the intended therapeutic purpose. Explanation of this difficulty could encourage patients to tolerate side effects if they perceive the overall balance to be in their favour.

"In a perfect world, all prescribers would explain the purpose and potential problems of each treatment for each patient. In practice this may require only minimal explanation, especially for short-term, acute illnesses. Generally, however, the extent of patient education required increases in direct proportion to the chronicity of the malady under treatment.

"At first glance, well-written medication information leaflets seem to provide the answer to many physician-patient information and communication problems. However, some of these leaflets seem to place undue emphasis on potential adverse effects so that the patient may become frightened and non-compliant. Printed handouts complement, but cannot replace, appropriate explanations by prescribers." (The role of the pharmacist in this area is discussed in section 8.1.)

"Paternalism has become unfashionable in theory, but in practice, many patients still prefer to trust their physicians rather than try to learn enough about treatment issues to

decide for themselves. If this delegation of responsibility occurs, it should be the patient's explicit or implicit decision."<sup>9</sup>

Patient education about all aspects of treatment is very important and is the responsibility of the whole health care team. Physicians generally begin this process when they obtain consent for treatment. The Inquiry supports an expanded role for pharmacists (section 8.1) in such education; the role of nurses (section 8.2) is also increasing appropriately. Poor communication between prescribers and patients, leading to bad outcomes, was stressed in many submissions.<sup>10</sup>

**7.1.1.1 The Physician: Patient Advocate or Gatekeeper for Society?:** Should physicians only be responsible to their individual patients or also to society at large? Legitimate concern about rising health costs highlights the role of physicians as designated guardians of society's resources. The ethical problems inherent in this role must be examined.

Pellegrino, an influential American medical ethicist, asks: "To what extent can, or should, the physician serve simultaneously the needs of his patients, his own interests, and those of society? To what extent should the physician be a double, triple, or even quadruple agent?" He concludes:—"There is in the nature of the medical transaction, an unavoidable gatekeeping function which the physician has always exercised and, indeed, is under compulsion to exercise in a morally defensible way. The unavoidable fact is that the physician recommends what tests, treatments, medications, operations, consultations, periods of hospitalization, or nursing homes the patient needs. Currently, the fact is that the physician monitors the flow of 75 per cent of today's health and medical care expenditure.

"This fact imposes a serious positive moral obligation on the physician to use both the individual's and society's resources optimally. In the case of the individual patient, the physician has the obligation, inherent in his promise to act for the patient's welfare, to use only those measures appropriate to the cure of his patient or alleviation of his suffering.

"The physician, therefore has a legitimate, indeed, morally binding responsibility as a 'gatekeeper'. He must use his knowledge to practice competent, scientifically rational medicine. His guidelines should be a diagnostic elegance—just the right degree of economy of means in diagnosis—and therapeutic parsimony—just those treatments that are demonstrably beneficial and effective. In this way, the physician automatically fulfils several moral obligations: he avoids unnecessary risk to the patient from dubious treatment and he conserves the patient's financial resources and society's as well."<sup>11</sup>

Pellegrino contrasts this traditional, desirable and acceptable gatekeeper role with external measures that deliberately interject economic considerations into the physician's clinical decisions. Pellegrino asks "is rationing inevitable?" The only argument with some moral substance is economic necessity. Disproportionately rising costs of drug treatment (and certain other interventions) in Ontario could be considered as threatening the availability of other health and social services.

If this line of reasoning is accepted, rationing becomes not only inevitable but, perhaps, defensible too. He also concludes "...that the integrity of the physician's primary responsibility to his patient is something society must preserve, rationing may not be as inevitable as generally supposed and that before we can

<sup>9</sup> OMA Committee on Drugs and Pharmacotherapy, "Informal Consent—The Drug Information Dilemma," *The Drug Report*, No. 21, February 1987.

<sup>10</sup> For example, by the Association of Jewish Seniors (brief #59-3100) which incorporated accounts of many individual experiences.

<sup>11</sup> Pellegrino, E.D., "Rationing Health Care: The Ethics of Medical Gatekeeping," *Journal of Contemporary Health, Law and Policy*; (1986), pp. 25-45.

impose rationing on morally valid grounds, all other means of cost containment must be exhausted.”<sup>12</sup>

It seems clear that the individual physician’s role is to act as advocate for the patient and to prescribe optimal rational pharmacotherapy. This must necessarily be tempered by the patient’s ability to pay when he or she is paying directly. When a third party payor is picking up the cost, the physician must either prescribe drugs that are covered by the plan, or make sure the patient is able and willing to pay any supplemental cost. This applies whether the third party is the Ontario Drug Benefit (ODB) program, an insurance company or another drug plan.

Which drugs are covered, and the way in which decisions about coverage are made, should be clear to patients or their representative (e.g. union negotiating team). When the taxpayer is ultimately responsible, as in the ODB, it is essential that taxpayers’ money be spent judiciously.

**7.3 The Committee therefore recommends to the College of Physicians and Surgeons of Ontario and the Ontario Medical Association, that individual prescribers be encouraged to remain advocates for, and responsible to, individual patients. Organized medicine, on the other hand, has a role in protecting society’s resources .**

**7.1.1.2 The Quantities of Drug Prescribed:** Each prescription instructs the pharmacist as to how much of the drug product to dispense; it may or may not allow the prescription to be repeated.

The quantity prescribed should ideally be individualized for each drug product for each patient and will vary from a single dose to

quantities sufficient to last an extended period of time. For an acute disorder it is often appropriate for the physician to prescribe a course of treatment likely to cure the problem; a repeat would not ordinarily be required. For on-going, chronic, and sometimes permanent conditions requiring long-term use of medication, the optimum number of doses is much less clear. When a new drug is to be used by a patient for the first time it is often appropriate for the initial quantity prescribed to be small. It is always possible that the “new” medication may not suit the patient and waste ensues if large quantities are prescribed initially. It is logical to regard all such “first prescriptions” as therapeutic trials for that patient.

For chronic and ongoing therapy there are a number of points to consider. The cost of the prescription includes both the price of the drug and the pharmacist’s dispensing fee. Clearly, total costs are minimized by reducing the number of repeat prescriptions so long as quantities prescribed are consistent with good medical practice and do not become so large as to lead to waste. For many years, the ODB program only allowed a 31 day prescription limit; this was changed in 1986 to allow quantities for up to 250 days. However, many physicians have never moved away from routinely prescribing monthly amounts.

An anonymous submission made the accusation: “Many physicians insist on seeing healthy patients every 30 days to maximize their billing frequencies. They prescribe only enough medication to allow the patient to get to the next office visit. No prescription renewals are allowed from these physicians. The patients do not understand that they are simply pawns in a chess game being used by the physicians to maximize their incomes.”<sup>13</sup>

<sup>12</sup> Ibid.

<sup>13</sup> Brief #21-3200.



Clearly, bad medicine is being practised where this occurs. However, there may well be sound medical reasons for the physician to see the patient monthly and correlation with the amount of drug prescribed can help monitor compliance. Sometimes it may be appropriate for the physician to allow repeats at weekly, or monthly intervals, for example, while relying on the pharmacist to monitor treatment.

In contrast, monthly prescriptions of long-term medication can waste resources if frequent monitoring is not necessary. The economics are as follows: Under the current legislation a prescription for a large volume (with the exception of short-term social assistance coverage for patients on general welfare) is to be dispensed in the quantity written. If the physician writes a prescription for 250 days supply, the pharmacist will dispense that amount and charge two dispensing fees.<sup>14</sup> However, many physicians will write the prescription for 30 days supply, with seven repeats (which will yield 240 days' supply). Under this situation, the pharmacist can charge eight dispensing fees—one for the initial prescription, and one for each repeat.

**7.4 The Committee therefore recommends that the Ontario Medical Association and the College of Physicians and Surgeons of Ontario, with input from the Ontario Pharmacists' Association and the Ontario College of Pharmacists, jointly study the appropriateness of the quantity of drugs on a prescription and issue appropriate guidelines.**

### **7.1.2 The Ontario Situation**

Having considered an ideal situation, and some theoretical aspects of prescribing, we now turn to the current practice in Ontario.

The Inquiry commissioned "A survey of the prescribing experiences and attitudes toward prescription drugs of Ontario physicians" (see appendices, volume II.) While the report which resulted from this survey gives illuminating insights into physician attitudes toward many aspects of drug treatment, its limits must be noted; it records subjective opinions rather than objective facts. As such, it does not provide hard evidence about the knowledge base that Ontario physicians possess regarding the proper use of drugs.

A number of findings emerge from the analysis in chapter four of the survey report:

"First, physicians estimate that roughly a quarter of the drugs they are familiar with do not produce results commensurate with their costs. While the survey data are insufficient to determine whether physicians avoid such drugs because they are too expensive in relation to their effects, or whether physicians still prescribe such drugs for lack of alternatives, this finding suggests a potential problem in the pharmaceutical marketplace. Interestingly, physicians also estimate that about half of the prescriptions they write are for generic drugs, suggesting both a concern for costs, and the perception that generics, in many cases, can be substituted for brand name products.

"Second, although demands from patients for prescription drugs and patients' expectations for a quick cure have been cited as important influences on physicians' prescribing decisions (Mahon and Godden, 1973; Schwartz, Soumerai and Avorn, 1989), physicians in the survey report relatively few requests from patients for drugs without proper consultation, and few prescriptions which are not medically necessary.

<sup>14</sup> The pharmacist is allowed one dispensing fee for up to 100 days' supply of a drug dispensed. 100-150 day's supply gives one and one-third fee, 150-200 one and two-thirds fee, and 200-250 two fees.

"Third, physicians report that roughly once for each four prescriptions written they counsel reductions in drug use, and that about half the time they discuss prescription drug utilization with their patients. However, high volume prescribers report that they counsel reductions and review drug therapies less often than those average rates indicate. Thus, significant numbers of prescriptions written in Ontario would not appear to be accompanied by specific discussions or reviews of the patient's drug use. The literature suggests that such discussions play an important role in ensuring prescribing quality (Schwartz, Soumerai and Avorn, 1989: 577).

"Fourth, large numbers of Ontario physicians report some involvement in profession-related events including seminars and continuing medical education courses which potentially provide them with relevant information about drugs and drug prescribing. The average Ontario physician attended three physician-sponsored seminars about prescription drugs in the two years before the survey. However, the frequency of government and professional reviews of prescribing practices is almost zero and there is little direct communication between prescribers and dispensers about the prescription drugs used by patients.

"Fifth, compared to their involvement in profession-related events, physicians report more extensive contacts with the pharmaceutical industry, another important source of information about prescription drugs. For instance, while physicians are contacted by pharmacists about once every six months, they are visited, on average, once every two weeks by pharmaceutical company representatives. Similarly, the average number of physician-sponsored seminars attended in two years is three; the average number of corporate-sponsored seminars

attended is just over five. And while high volume prescribers tend to be involved in more profession-related events than physicians prescribing fewer drugs, they are also more likely to have contacts with the pharmaceutical companies, and these latter contacts are substantially more numerous. On average, physicians who write more than 70 prescriptions per week are visited by pharmaceutical company representatives once each week. Since information transmitted to physicians during the course of such contacts is likely to be as much promotional as educational, designed to promote the sale and utilization of specific pharmaceutical brands, this pattern of results raises questions about the objectivity and accuracy of information physicians have about prescription drugs (Carruthers, Goldberg, et. al., 1987: 178; Lexchin, 1988; Thompson, 1988).

"Sixth the apparently greater attractiveness of industry-sponsored, as opposed to profession-sponsored contacts, may be in part a function of the range of benefits offered to physicians by the industry. Significant numbers of Ontario physicians report that they accepted benefits from pharmaceutical companies in the two years before the survey. Among the most frequently reported benefits are meals and stationery; travel expenses and office services are least frequent. Just under 3 per cent say that they received computer hardware or software from the industry. It is important to note that in January 1989, in the period before the survey was conducted, the College of Physicians and Surgeons of Ontario informed all physicians in the province that the receipt of benefits from corporate sources constituted a potential conflict of interest and that physicians accepting such benefits could be disciplined. The estimates reported in this chapter may therefore tend to minimize the extent of benefits received."<sup>15</sup>

<sup>15</sup> Report on the 1989 survey of the prescribing survey of the prescribing experiences and attitudes toward prescription drugs of Ontario physicians by A. Paul Williams, and Rhonda Cockerill, p.31.

**7.1.2.1 Attitudes of Ontario Physicians to their Education “as a preparation for prescribing drugs”:** In addition, physicians participating in the commissioned survey were asked to assess the adequacy of their formal, medical training as the basis for their own professional practices, to comment on the relative importance of various sources of information about prescription drugs, and to identify problems affecting their capacity to remain current in terms of professional knowledge in this area. The major findings in chapter 5 of the report can be summarized as follows:

First, while three-quarters of Ontario physicians rated their undergraduate medical education as an adequate basis for prescribing drugs, the remaining one quarter rated it as inadequate.

Second, in spite of these positive assessments of medical education, many physicians indicated that they are dissatisfied with their current knowledge of key aspects of prescribing. For instance, while two thirds of Ontario physicians are satisfied with their knowledge of drug effectiveness, only 15 per cent are satisfied with their knowledge of drug costs. Fewer than one quarter are satisfied with their knowledge of equivalencies of similar drugs or competing brands of the same drug; just over a third are satisfied with their knowledge of alternative non-drug therapies.

On the one hand, the majority of physicians say that they are satisfied with their medical training and the quality of information they receive on the effectiveness of the drugs they prescribe. On the other hand, only a minority indicate that their prescribing decisions are informed by what they believe to be satisfactory levels of knowledge about drug costs, drug alternatives, or alternative therapies not involving drugs. A lack of information in these areas, while not necessarily resulting in inappropriate prescribing, could mean that

prescribing decisions are made without adequate consideration of the full range of treatment alternatives, including those which do not involve prescription drugs.

Third, although they are less than completely satisfied with their current knowledge about prescription drugs, only a minority of physicians identify problems in “keeping up” their professional knowledge in this area. About one in four evaluated the rate of introduction of new drugs, concerns about the credibility of available information, and the difficulty in assessing this information, as serious problems. However, one-third of all physicians, and half of the highest volume prescribers, judge “lack of time” as a serious problem. With large patient loads, time available to physicians for continuing education and for counselling patients decreases. Coincidentally, prescription volume and prescription density estimates increase with larger patient loads.

Fourth, professional meetings and journal articles are judged by the majority of physicians as important sources of information about prescription drugs in their own practices. Although the data in chapter 4 of the survey show that Ontario physicians attend, on average, just over one continuing medical education course per year, two thirds rate such courses as important information sources. Conversely, while physicians have relatively frequent contacts with the pharmaceutical industry, only a minority state that involvement in company-sponsored seminars, and contacts with drug company representatives, are important information sources.

Fifth, physicians who write the largest number of prescriptions, and thus have a disproportionate influence on aggregate patterns of drug utilization in the province, appear to have more significant problems than other physicians with key aspects of their current knowledge about prescription drugs and more serious problems “keeping up.”



They are also most likely to say that lack of time is a serious problem. The literature suggests that lack of time may be strongly and inversely related to prescribing quality (Schwartz, Soumerai and Avorn, 1989).

While attending more profession-sponsored courses and seminars than other physicians, high volume prescribers also have significantly more contact with the pharmaceutical industry, receive a wider range of corporate benefits and judge industry contacts as relatively more important sources of information about prescription drugs than do other physicians. This does not necessarily argue that industry contacts or industry-sponsored benefits cause physicians to prescribe inappropriately or in high volume. It does indicate that when faced with lack of time and uncertainty, familiar sources of information may have an important influence on prescribing decisions (Carruthers, Goldberg et. al., 1987: 178). Physicians who rely more heavily on drug company sources for their information have also been identified in the literature as less rational prescribers (Lexchin, 1988).<sup>16</sup>

### 7.1.3 Education of Physicians for Pharmacotherapy

The educational system for health care professionals clearly needs to emphasize "learning to learn" as well as the scientific and professional curricula. Rapid continuing change seems certain and all health care professionals must be prepared for it during their formative years. We believe the education of physicians about drug therapy to be less than satisfactory at present.

Many submissions to the Inquiry stressed the key role of physician education in achieving the goal of optimal therapy.<sup>17</sup>

Education, as it relates to therapeutics, can be divided into undergraduate, post-graduate and continuing medical education segments. During each of these periods of education for rational pharmacotherapy the goals to be achieved must be clearly defined, the methods of achieving these goals considered, and the milieu and sources of information determined, so as to provide comprehensive, accurate and impartial drug information which will promote rational prescribing habits. The interplay of student (or physician) and instructor(s), and the principles of drug evaluation and usage on which therapeutic decision-making is taught, should continue to guide prescribing throughout the physician's career. For their entire professional lives, physicians must evaluate critically the claims made in the promotion of drug products. Less basic pharmacology is taught in Canadian than in the American medical schools, and wide variations exist in the amount of formal instruction in clinical pharmacology. A recurring theme is the inadequacy of some medical school trainees in the daily application of knowledge of drugs in real-life situations.

It is increasingly difficult for physicians to keep abreast of important developments in pharmacology, although pharmaceutical companies have been quick to fill this educational gap. It is estimated that American pharmaceutical firms spend some \$5,000 per physician per year to encourage use of their products. Survey figures of the Pharmaceutical Manufacturers Association of Canada suggest that the amount spent here is between \$6,500 and \$10,000.

Although about half the graduates of the Canadian medical schools will practice as primary care physicians in the community, all students are trained primarily in large

<sup>16</sup> Schwartz, R.K., S.B. Soumerai, J. Avorn: "Physician motivations for nonscientific drug prescribing." *Social Science and Medicine*, 28:6 (1989), pp. 577-582.

<sup>17</sup> OMA, Medical Reform Group, Association of Jewish Seniors and others.

teaching hospitals where most teaching involves acutely ill people with serious illness. Education about appropriate treatment strategies for such patients does not necessarily prepare physicians well for community practice. In the community, illness tends to be more chronic or self limiting, and frequently calls for a different therapeutic approach.

In some universities, attempts are being made to help integrate clinical with basic pharmacology, to assist students to develop better problem-solving skills and become more familiar with reference sources.

**7.1.3.1 Undergraduate Education for Pharmacotherapy:** Medical students receive formal instruction in the basic principles of pharmacology and therapeutics during their medical undergraduate years. We believe courses should be modified so that in addition to basic principles of prescribing, sessions are devoted to special issues in pharmacology, including those related to geriatrics. Issues such as multiple symptom control, compliance, multiple disease effects, drug interaction and adverse drug reactions, should be highlighted. The role of pharmacists and pharmacologists can be introduced at this point and the issues of polypharmacy stressed.

This initial exposure to pharmacology and therapeutics, usually introduced in the first year, should be followed, during the next two clinical years (prior to clerkship) with specific focused sessions on drug usage and specific problems as each of the systems (cardio-vascular, respiratory, gastro-intestinal) are dealt with. Sessions devoted to the evaluation of drug usefulness, and the issues involved in the introduction and use of new drugs, are necessary to help students learn how to make best use of information supplied by pharmaceutical companies. Methods of critical evaluation of drug usage and cost/benefit/effectiveness should become part of a medical

student's approach to prescribing. Prescribing strategies should be, but rarely are, discussed in medical pharmacology courses.

The clerkship year should contain a number of didactic sessions from physicians skilled in general and geriatric drug prescribing, as well as from pharmacists/pharmacologists, in order to develop the basis for a proper working relationship and knowledge of the synergistic role of the professions. During the clerkship year, specific clinical experience in geriatrics should be provided and emphasis on drug prescribing and its rationale and consequences should be included. (This is discussed in greater detail in chapter 11).

**7.5 The Committee therefore recommends that the Council of Ontario Faculties of Medicine encourage educational initiatives at each of Ontario's medical schools to include:**

- a) Pilot studies to determine the effectiveness of changes in undergraduate and postgraduate curricula which emphasize the cultivation and maintenance of good prescribing practices;
- b) Greater integration of basic and clinical sciences, in particular integration of pharmacotherapy with pharmacology;
- c) Greater recognition by clinical specialist departments of the differences in the pattern and types of morbidity found in university teaching hospitals and community practice;
- d) More emphasis on critical appraisal of drug products throughout the medical curriculum; and
- e) More emphasis on the specific medical problems and treatment needs of the elderly. (See also chapter 11.)

**7.1.3.2 Internship and Residency Education for Pharmacotherapy:** During the post-graduate period (internship and residency) many lifelong prescribing habits will be formed. Much is learned on an “apprenticeship” basis, with the responsibility of teaching delegated to the clinical teachers who guide interns and residents through these years. Good role models are essential.

One year (soon to be increased to two) of internship is required for all physicians before licensure in Ontario. During the various rotations involved in an internship most aspects of drug prescribing are supposed to be learned. Unfortunately, this is not always the case since very much depends on the strengths, weaknesses and special interests of the staff physicians and hospitals organizing the internships. For example, there is likely to be too little formal exposure to the medical problems of geriatric patients and to the principles of geriatric drug prescribing. All interns should have formal exposure to geriatric medicine and specific instruction in the principles and practices of rational drug use by the elderly.

The residency period is that time when a physician in training focuses on an area of dedicated study and learns the body of knowledge appropriate to that specialized field. This involves three to five years of additional clinical experience. Interns and residents should learn the essentials of proper drug audit procedures.

Formal rotation at the resident level in a geriatric service and long-term care facility, with a special emphasis on drug prescribing, should be a mandatory part of the core period in internal medicine. A specific geriatric rotation should also be included in the core training of residents going into surgery and/or anaesthesia although, if properly organized, the internship experience may be adequate for this purpose. (See chapter 11.)

**7.6 The Committee therefore recommends that educational initiatives at the medical postgraduate level include:**

- a) Regular review of pharmacological aspects of therapy;
- b) Improved integration of clinical pharmacology in all services including surgical units;
- c) Improved audit procedures regarding the use of drug products (see also drug utilization review); and
- d) A specific geriatric experience at either intern and/or residency level.

**7.1.3.3 Continuing Medical Education:** The method by which physicians receive continuing education once they enter practice is critical to the assurance of ongoing sound drug prescribing. Maintaining an appropriate knowledge base is necessary. Because of wide individual variations in the way people learn best, there should be a variety of options open to prescribers.

The process of continuing medical education is complex and includes the integration of drug information from various sources. Physicians’ prescribing habits are influenced by personal experience; reading; exposure to advertising; through peers and consultants; lectures, seminars and courses; pharmaceutical company representatives; patient pressures; attendance at pharmaceutical company sponsored educational sessions; and specific prescription-oriented literature.

Each of these methods of receiving new information is used in varying degrees by practising physicians. In academic settings, lectures and seminars, the medical literature and discussions with colleagues probably play the greatest role in maintaining the knowledge base and implementing change. For physicians in community practice, there may be more dependence on formal



educational seminars (through hospital grand rounds, etc.), on pharmaceutical company advertising, pharmaceutical representatives and industry-sponsored seminars, and on discussions with colleagues and special consultants. A variety of journals and tapes may often be a major resource.

Pharmaceutical manufacturers are well aware of the impact that specialists and respected consultants have on the prescribing habits of community physicians, and direct a great deal of effort to promotional activities aimed at specialists.

While these sources of information may expose physicians to an array of choices, there should also be an unbiased source of prescribing information to provide appropriate prescribing data and evaluate and compare various alternatives, not only for therapeutic efficacy and side effect profile, but for relative cost/benefit. This resource, frequently updated, with the essential features to assist physicians in general prescribing decisions, and with a special emphasis on issues related to the older patient, should be available to all physicians.

With the continued growth of the pharmaceutical industry, the number of new drug products will continue to expand considerably. Better methods will have to be developed to ensure that health care providers have easy access to information that assures rational prescribing. The traditional reliance on scientific articles in medical journals, coupled with the innovators' advertising, may not give a sufficiently balanced perspective.

Regular updates on various aspects of pharmacotherapy are published in a variety of journals catering to both general and specialist prescribers. If "Choice of Medications—Ontario 1990" is to be published, (see recommendation 7.9) regular monthly updates would be desirable and

could be included in the existing Ontario Medical Association (OMA) publication "The Drug Report."

A method of integrating the drug prescribing, dispensing and record keeping systems of physicians and pharmacists would be very useful. A comprehensive computer-based system would allow a proper drug utilization program to be implemented. Such a system would be a powerful tool encouraging continuing medical education, but it should not be used in a punitive fashion. The most effective outcome would be its mutual acceptance as an educational tool.

Education can be effective in producing a sustained impact on prescribing practice. Drug utilization review is an essential element of the educational process since it provides the informed basis for dealing with real problems. There is little hard evidence that sustained changes in drug prescribing behaviour are achieved by drug bulletins, awareness campaigns, lectures, seminars, video or audio tapes, price lists, reminder notes or checklists, decision-making algorithms, handbooks, guidelines, mailed brochures and "unadvertising" alone. However, despite the lack of "proof," we believe that educational projects and guidelines such as "Choice of Medications—Ontario 1990" are useful.

There is reasonable evidence that sustainable effects on drug prescribing can be achieved by designing interventions that: 1) are specifically designed, based on actual patterns of prescription by individual physicians in the local practice environment; this requires some type of audit process, such as drug utilization review; 2) target heavy prescribers; 3) focus on specific drugs such as antibiotics or tranquilizers, when these are prescribed erratically or idiosyncratically; 4) make use of special interventions such as unbiased detailing;

5) incorporate feedback to individual physicians on their drug prescribing patterns'; and 6) include verbal counselling of individual physicians.

The willingness and ability of the medical profession at large to accept or implement such systems is unknown and the Committee believes that a great deal of attention to these aspects will be needed. However, we are encouraged by the positive attitude of a number of physicians with whom we have discussed this.

### **7.7 The Committee therefore recommends that:**

- a) **The Council of Ontario Faculties of Medicine, the Ontario Medical Association and the College of Physicians and Surgeons of Ontario be asked, by 1991, to develop new, imaginative and effective programs in continuing medical education which will encourage participation of a greater proportion of physicians; and**
- b) **That the Council of Ontario Faculties of Medicine, in conjunction with the Drug Quality and Therapeutics Committee, the Pharmaceutical Manufacturers Association of Canada, the Canadian Drug Manufacturers Association, Health and Welfare Canada, Canadian Pharmaceutical Association and the Ministry of Health be asked to develop, by 1993, innovative post-marketing surveillance studies, of a variety of pharmaceutical preparations, both brand names and generics, and involving large numbers of family practitioners.**

## **7.2 The Role of Government and Medical Associations**

Earlier, we endorsed the role of the individual physician as the unreserved advocate for the

individual patient. We now consider the role of organized medicine.

A basic strategy should be to make it as easy as possible for the physician to prescribe well and to discourage less appropriate prescribing. In this section we discuss and give our reasons for supporting: 1) Appropriate guides to treatment; 2) The publication of "Choice of Medications—Ontario 1990"; 3) "Restricted use" of expensive medications where acceptable alternatives exist; 4) The continued development of restricted hospital formularies; and 5) The extension of the restricted formulary approach to group clinics, nursing and old age homes, health maintenance organizations and comprehensive health organizations.

In each of these instances, it is imperative to ensure full medical input, as well as contributions from pharmacy and the other health care professions. The method of decision making should be clear and widely known to all concerned.

We also briefly discuss the drug name problem, treatment review requirements, detailing of drug products, the role of the clinical pharmacologist and prescriber/ pharmacist relations.

### **7.2.1 Appropriate Guides to Treatment**

The central promulgation of 'standards', 'norms' or 'parameters' for clinical care can understandably be threatening to individual health care professionals and to the patients they serve. Rigid and inappropriate standards can interfere with the proper doctor/patient relationship, can make it more difficult to individualize treatment, can lead to less than optimal treatment if clinical judgement suggests deviation from "standard" and can, ultimately, lead to a poor outcome for the patient. Although adequate studies of 'outcome' review are highly desirable they are very often not available and prescribers must

choose the 'best buy'.<sup>18</sup> As part of the approach to rational pharmacotherapy, the health care professions should define guidelines for efficient and appropriate medical care.

"It is now clear that the enormous complexity of medical advances often exceeds the capacity of any individual physician to read the voluminous literature, analyze the complex data, and synthesize an optimal practice pattern. For example, not one doctor in a thousand has the time or training to produce the recently distributed guidelines for the testing and treating of asymptomatic hypercholesterolemia, which were designed to identify and promote exemplary clinical practice. This document also identified cost considerations, but cost did not at any time supersede considerations of quality of care. The OMA has also successfully developed guidelines for in-vitro fertilization and for the use of coronary thrombolytic agents; in each case optimal clinical practice was the primary objective."<sup>19</sup>

**7.2.1.1 Guideline for Guidelines:** "Guideline for guidelines"<sup>20</sup> as they apply to the medical practice have been articulated by the OMA and they suggest:

1) Guidelines for medical practice are written to help improve the quality of care. They must never be rigid standards because individual variations, and the diversity of good medical practice, do not permit standardization. Guidelines for medical practice must not include restrictive definition of details, such as expected length of hospital stay, or impose limits to permitted testing or treatment. They must never become parameters which could be used by funding agencies to restrict the provision of care to patients who need it.

2) Guidelines must be voluntary and permissive.

3) Guidelines should incorporate sensible economic evaluation of drugs, technology or procedures, but must not promote the restriction of an effective therapy for purely fiscal reasons.

4) Guidelines must be sensitive to social and humanitarian considerations and must be open to criticism and debate by the medical profession, by other health-care providers and, where appropriate, the public.

5) Guidelines clearly apply to restrictions on limited prescribing, such as treatment protocols and restricted formularies. It should be noted that guidelines directed at optimal clinical practice may well promote increased expenditure rather than constraining costs.

The OMA goes on to emphasize the necessity of involving specialty societies and others: the Royal College of Physicians and Surgeons, the College of Family Practice, the universities, the College of Physicians and Surgeons of Ontario and other disciplines as appropriate. Guidelines must clearly be subject to constant review as advances in medical management occur.

Although its primary objective remains first class care for patients, the medical profession can no longer ignore the cost of expensive drugs or procedures. But as we have shown, it is not always easy to balance quality of individual care and the good of society as a whole.

**7.8 The Committee therefore recommends the development, by the profession of medicine, through its various organizations, of appropriate guidelines to treatment.**

<sup>18</sup> Whitehouse, J.M.A., "Best Documented Practice," *British Medical Journal*, 298, (1989), pp. 1536-7.

<sup>19</sup> Linton, A.L., Supplementary Report to Council, OMA, May 15, 1989.

<sup>20</sup> Linton, A.L., "Guidelines for Medical Practice I," and David Peachey & A.L. Linton, "Guidelines for Clinical Practice II: A possible strategy," (Submitted to the Canadian Medical Association Journal for publication.)



### 7.2.2 “Choice of Medications— Ontario 1990”

The Inquiry’s third interim report stated: “Ontario physicians do not have ready access to a concise but informative up-to-date and impartial guide to prescribing as there is no Canadian equivalent to such publications that have proved useful elsewhere in the world. While basic textbooks of pharmacology are available and there is much literature provided by pharmaceutical manufacturers, as the OMA reported, it is increasingly difficult for physicians in practice to keep abreast of....hundreds of new products which have been introduced in the last decade. The OMA has recommended, and is willing to take the lead in, the development ‘of a publication that would provide a basic guide to effective and economical pharmacotherapy.’ This is envisaged as a concise, authoritative publication compiled by an editorial board comprised of appropriate independent health care professionals (clinical pharmacologists, nurses, pharmacists and practising physicians.)”

The name “Choice of Medications—Ontario 1990” has been suggested. The need for such a publication is reinforced by the 1989 survey of Ontario physicians which demonstrated that only 15 per cent of respondents were satisfied with their knowledge of drug costs.

Information provided by pharmaceutical manufacturers, such as that found in the “Compendium of Pharmaceutical and Specialties,” (CPS) will continue to be useful and reliable. The CPS, however, does not consider costs and does not attempt to select “best choices” within therapeutic categories. It does, however, give a wealth of detail and is especially useful as a reference work and guide once a particular drug product is chosen.

**7.9 The Committee therefore recommends that “Choice of Medications—1990” be**

**published and made available, on an annual basis, to all licensed physicians and pharmacies in Ontario. The publication should contain guidelines for prescribing based upon objective information about preferred drug products, including their indications, contraindications, side effects, recommended dosages and relative costs.**

Physicians would, of course, remain free to prescribe any approved medication if, in their view, the preferred medications are not appropriate in specific cases.

### 7.2.3 Restricted Use of Expensive Medications

In the first quarterly report, the Committee suggested the abolition of “special authorizations” and the development, by the Drug Quality and Therapeutics Committee (DQTC), of a “restricted use” category for some drugs. “Restricted use” means that the physician must be willing to certify that the drug is being used in the manner, and for the specific use, listed in the ODB formulary. Physician compliance can be assured by the usual peer review procedures. Despite criticism from the pharmaceutical industry, it appears this is a sound concept, acceptable to most patients and physicians. It seems imperative that society gets the best possible value for tax dollars spent on health care services. Development of a restricted category does not restrict a patient’s right to be treated with an expensive drug for indications other than those authorized in the formulary. It does, however, mean that the taxpayer does not have to pay in such cases.

**7.10 The Committee therefore recommends that the Ministry of Health continue to be guided by the DQTC as it develops the “restricted use” concept in the Ontario Drug Benefit formulary. (See also recommendations 4.2 and 4.3.)**

### 7.2.4 Restricted Hospital Formularies

Many presentations at the Inquiry's open hearings emphasized the value of relatively restricted hospital formularies. The contrary view was expressed by the pharmaceutical manufacturers, who take the position that any approved legal drug should be available in hospitals, regardless of cost.

The Inquiry believes that restricted hospital formularies have proved beneficial, by both improving the quality of pharmacotherapy and conserving scarce resources. Most hospitals in Ontario are believed to have effective formularies and their constant updating and improvement should be encouraged.

**7.11 The Committee therefore recommends that the Ontario Hospital Association be asked to foster the continued development and use of restricted hospital formularies.**

### 7.2.5 Restricted Formularies Out of Hospital

The success of the restricted hospital formulary concept encourages its extension to other situations. Whenever an organized medical staff can, with pharmacist support, set up a "drugs and pharmacotherapy committee," the development of an agreed restricted formula may be appropriate. A key ingredient for success is likely to be the level of physician involvement and enthusiasm for the project in the local setting.

**7.12 The Committee therefore recommends that the Ministry of Health, the Ontario Medical Association and the Ontario Pharmacists' Association promote the extension of the restricted formulary approach to group clinics, nursing and old age homes, health maintenance organizations and comprehensive health organizations.**

### 7.2.6 Drug Names

There is no possibility that any action taken in Ontario can resolve the world-wide difficulties with drug names but rational pharmacotherapy is probably best served when all concerned use non proprietary (generic) names for drug products.

Any drug may be named as:

1) A chemical entity. The full chemical name is useful for the chemists who manufacture and study it, but practically useless for prescribing.

2) A non-proprietary or generic name. The term generic really means "part of a family" and should properly be used when discussing a class of drugs, eg. "a sulphonamide," "a benzodiazepine." In Ontario the use of "generic," as meaning non-proprietary, seems well established and we so use it in this report.

3) A proprietary or brand name. This defines a trade mark applied to a drug product that is a particular formulation of a chemical by a particular manufacturer.

Clinical pharmacologists world-wide advocate the habitual use of non-proprietary names in prescribing. This promotes economy, reduces confusion when patients travel to another country where brand names are different, and usually gives some information as to the class of drug prescribed.

We support this. Nevertheless, because new drugs when first introduced are usually known by the innovator's proprietary name, all concerned have to learn at least two names for many drugs. [The proprietary and the non-proprietary (generic) names.] Use of non-proprietary names is not a panacea for avoiding medication errors and can even increase confusion. For example cefotaxime (proprietary Claforan) can easily be confused

with cefoxitin (proprietary Mefoxin) if non-proprietary names are used. Use of the brand name would obviate confusion in this type of situation.

**7.13 The Committee therefore recommends that the use in Ontario of non-proprietary (generic) drug product names be encouraged in the writing and labelling of prescriptions, except where there is a special reason to use a brand name.<sup>21</sup>**

### 7.2.7 Treatment Reviews

Steadily increasing numbers of Ontarians, especially the elderly, are properly being treated with long term pharmacotherapy. This is happening because previously fatal illnesses are responding to treatment (eg. ischemic heart disease and diabetes.) People seldom die young of infectious disease nowadays but live on to suffer from degenerative illness. Much morbidity and stress can be, and is, alleviated by long term pharmacotherapy for many of these people. Treatment must, of course, be individualized and needs to be reviewed and reassessed at appropriate intervals. The optimal frequency of review varies from patient to patient.

Such review is greatly helped when:

- one physician—often the family practitioner—is coordinating the treatment and keeping proper records;
- the patient brings in the medication at each visit, especially if hospital admission becomes necessary;
- medication lists are prepared and updated. (“Smart cards,” which provide computerized access to the patient’s drug profile may, in the near future, prove to be very useful); and

- the patient selects a regular pharmacy and the family pharmacist and the family physician communicate regularly.

Patients in hospitals and other institutions also need their drug treatments regularly reviewed. In an acute hospital situation, such a review may be necessary many times a day or, indeed, minute by minute (e.g. when cardiac shock due to a dysrhythmia is treated.) At the other end of the spectrum is the patient who will need to be treated for the rest of his or her life (eg. hypothyroidism), where a yearly assessment may be enough once an initial baseline has been established. It is probably not possible to regulate optimal review except to state that appropriate, deliberate and planned review is clearly necessary.

Despite the best efforts of all concerned, some adverse drug reactions are inevitable. Their recognition and reporting is an important part of the treatment review process (see section 9.3.)

The special problem of the long term use of sedatives, hypnotics and tranquilizers is discussed in chapter 9. In this area, regular review is especially important and it may require extra effort to obtain patient co-operation and compliance.<sup>22</sup> The Inquiry recognizes that treatment review is an integral part of rational pharmacotherapy and believes that considerable improvement is possible in this area.

**7.14 The Committee therefore recommends that the Council of Ontario Faculties of Medicine, the College of Physicians and Surgeons of Ontario, and the Ontario Medical Association be asked to promote regular, appropriate, organized reviews of drug treatment.**

<sup>21</sup> OMA and Medical Reform Group.

<sup>22</sup> Cohen, Howard “Medication and the Elderly—the Role of the Family Physician,” brief #118-3100, Council on Aging of Ottawa–Carlton.



## 7.2.8 Detailing

Drug detailing by sales representatives who promote specific products is part of the competitive world of innovative drug manufacturing. For this reason, it inevitably fails as an unbiased source of information about drugs for prescribers. Drug detailing is accepted as part of the current health care scene world wide, and it is not realistic to advocate its abolition in Ontario, as some briefs to the Inquiry have recommended. It is also unrealistic to ban all forms of drug company advertising.

Although promotional drug detailing will undoubtedly continue, we believe it can be improved. The accredited pharmaceutical manufacturers' representative program, established by the industry, is an important first step in the professionalization of sales representatives. Accreditation can be built upon by increasing the breadth and depth of knowledge of the representatives, many of whom have already become trusted sources of information for prescribers. This type of trusting relationship with physicians and pharmacists clearly depends on the professional expertise and integrity of the representative, the promotion only of good products, and a helpful, realistic attitude...all attributes which would be enhanced through upgrading the detailing function.

An important part of both undergraduate and post graduate physician education about pharmacotherapy involves learning how to assess and compare the various treatment options. Learning to critically assess the information provided by pharmaceutical representatives should be part of this.

The pharmaceutical industry has found detailing to be a highly effective way of

altering physician behaviour. As indicated earlier, the combined expenditures of pharmaceutical manufacturers to promote their products total \$6,000 to 10,000 per year per physician. An important portion of this expenditure supports detailing. For rational prescribing to occur consistently, there may have to be some countervail to product-biased detailing.<sup>23 24</sup> An effective and cost effective American model exists but has not been widely applied.<sup>25 26</sup> In this model, physicians are "detailed" (informed) about selected problem areas of pharmacotherapy by unbiased specially trained pharmacists whose salaries are not paid by specific manufacturers. There could be problems translating the model to Ontario because at this time there may not be enough pharmacists with the necessary training and skills. Clearly, this human resource problem could be remedied in the future if this model were shown to be effective, and if there is the will to do so.

**7.15 The Committee therefore recommends that, by 1992, the Ministry of Health establish pilot projects to test unbiased detailing in Ontario, based on the Harvard model. Consultation with the Ontario College of Pharmacists, the Ontario Pharmacists' Association, the College of Physicians and Surgeons, the Ontario Medical Association and the pharmaceutical industry should precede this.**

## 7.2.9 Guidelines for Industry

The attitudes of Ontario physicians to the educational and promotional endeavours of the drug companies, as surveyed in 1989, are discussed on page 102. Drug company "inducements" to prescribers have varied from the purely educational (and acceptable) to the unacceptably expensive hospitality that

<sup>23</sup> Lexchin, J. *International Journal of Health Services*, 19:4 (1989), pp.663-679.

<sup>24</sup> Schwartz, R.K., S.B. Soumerai, J. Avorn, "Physician motivations for non-scientific drug prescribing," *Social Science and Medicine* 28:6 (1989) pp. 577-582.

<sup>25</sup> Soumerai, S.B. & J. Avorn, "Economic and Policy Analysis of University-based Drug 'Detailing'." *Medical Care* 24:4 (1986), pp.313-331.

<sup>26</sup> Avorn, J. & S.B. Soumerai, "Improving Drug Therapy Decisions through Educational Outreach", *New England Journal of Medicine*, 308:24 (1983), pp. 1457-1463.

has become notorious. There is little to suggest that the vast majority of practising Ontario physicians fail to prescribe ethically. Professional standards of practice are maintained by the College of Physicians and Surgeons of Ontario, which also evaluates practice patterns and implements disciplinary action where appropriate.

In the area of post marketing evaluation of drug utilization, some physicians may be persuaded to engage in activities that could compromise the traditional principles of medical ethics and standards of practice. Steps must always be taken to ensure that there is no undeclared conflict of interest, or personal gain, on the part of a physician supervising a drug trial. Financial support for such activities should be structured so that participating physicians have no major personal financial stake in the issue. Remuneration for participating in the trial should be limited to compensation for time actually committed to the trial.

Physicians must also carefully consider the impact of other drug company supported activities, including seminars and conferences with major social activities. Gifts of various kinds, and payment for “educational” activities, should be kept in perspective. Support for educational activities from pharmaceutical companies should be utilized as objectively as possible and physicians should not be seen as “endorsing” any particular product line in connection with continuing medical education activities.

In general, physicians should not accept any reward or remuneration from a drug company unless they would be comfortable if peers and patients knew about it.

Drug company advertising in professional journals has been criticized in Canada and elsewhere but it is now well established as part of the world-wide innovative drug development scenario. The free market

system has produced most of the effective new drugs which have improved treatment options, and we do not believe that restricting such advertising would, on balance, be in the public interest.

Federal legislation, together with the industry’s own endeavours to regulate advertising, may have reduced inaccurate claims but seem to have done little to raise the tone above a “hard sell” sensational level. Prescribers, like other Ontarians, might well regard themselves as immune to exaggerated claims of great benefits for a drug with little or no risk. However, if this type of advertising were not effective, it seems doubtful that manufacturers and their advertising agencies would persist. Again education of physicians, both initial and ongoing, is the best defence.

**7.16 The Committee therefore recommends that, by 1991, the College of Physicians and Surgeons of Ontario, after consultation with the Ontario Medical Association and the pharmaceutical industry, develop and publicize ethical guidelines for physician/industry interaction, which also deal with the industry’s involvement in continuing medical education.**

#### **7.2.10 Clinical Pharmacologists**

It has become clear to this Inquiry that the province needs many more clinical pharmacologists. Major roles for clinical pharmacologists include direct teaching of both physicians in training and their clinical supervisors; organizing appropriate continuing medical education for practising physicians; leading drug utilization monitoring programs; and continuing research. More clinical pharmacologists and more departments of clinical pharmacology will clearly cost money. In the long run they should save money by promoting rational pharmacotherapy.

There also appears to be an increasing need for institution-based pharmacists to be involved in teaching and monitoring drug usage in both academic and non-academic hospitals as well as in many long-term care settings.

In its submission, the Council of Ontario Faculties of Medicine (COFM) recommended: “the creation within Ontario of a network of clinical pharmacology education units. Such units should ideally be created in each of the five health science centres. They should bring together, within one program, a number of disciplines, as appropriate to the individual centre. These education units should be charged with the responsibility for undergraduate, postgraduate, and continuing education of health professionals. They should have a major responsibility for the development of clinical teaching units focused on optimal drug prescribing in each centre.

“The centres should have further responsibility for leadership in public education and for eventual recruitment of a network of dedicated ‘advisers’ on drug therapy who would function in a broader health region. They should be responsible for the training and later maintenance of competence for such drug advisers. Such advisers would, in turn, be expected to work with district health councils in development of community-based approaches likely to improve drug prescribing. Initially, the emphasis should be on education and training with the necessary supportive health care delivery research. The size of a clinical pharmacology education unit might vary from centre to centre, but should include a critical mass of clinical pharmacologists, clinical epidemiologists, toxicologists, clinical pharmacists, and health economists working

in collaboration with scientists interested in pharmacology toxicology and pharmaceutical sciences.”<sup>27</sup>

The Inquiry found this recommendation by COFM persuasive.

**7.17 The Committee therefore recommends that the Ministry of Colleges and Universities be asked to promote and fund the establishment of a department of clinical pharmacology in each Ontario medical school. These should be closely linked to the centre for the study of drug prescribing (see recommendation 7.2.)**

#### **7.2.11 Prescriber/Pharmacist Relationships**

Lack of adequate prescriber-pharmacist communication and prescriber/pharmacist friction are highly undesirable and potentially dangerous for the consumer.

Fortunately, at the organizational level the relations between prescribers and pharmacists in Ontario are excellent, as judged by the co-operative attitudes of their organizations (OMA, and the College of Physicians and Surgeons of Ontario (CPSO) with the Ontario Pharmacists’ Association (OPA) and the Ontario College of Pharmacists (OCP).) Issues relating to pharmacists are considered in chapter 8, but in the context of prescribing it seems important to emphasize that local prescriber/pharmacist interaction is important. This is much easier to achieve in a hospital, or in a small town, than in Ontario’s cities.

According to the report on the 1989 Survey of the Dispensing Practices and Attitudes Toward Prescription Drugs of Ontario Pharmacists (see appendices, volume II):

<sup>27</sup> Brief #52-3100.



“Many feel that the pharmacist/prescriber relationship needs improvement. Pharmacists feel that physicians have a poor understanding of what they actually do, especially in relation to over-the-counter drugs. Frequently, pharmacists believe doctors over-prescribe, especially narcotics. They would like physicians to be more accountable for what they prescribe.

“One respondent remarked that Ontario is the only province where an agent for a doctor can phone in a prescription. Apparently some physicians are unwilling to answer calls from pharmacists and/or discuss drug therapies.

“There was also a suggestion that prescribers should have more information on the cost of various drug treatments. A number of pharmacists remarked that it would be useful for prescriptions to list a diagnosis/reason for treatment; this would be extremely useful when counselling patients.”

In its fourth interim report, this Committee recommended that the pharmacist, when clinically appropriate and with the agreement of the patient, has access to the patient's diagnosis(es).” (See chapter 8).

This recommendation, and the recommendations for increased counselling by pharmacists, have the potential to lead to friction because of the perceived threat to physician autonomy.

**7.18 The Committee therefore recommends that the Ontario Medical Association, the Ontario branch of the Canadian Society of Hospital Pharmacists and the Ontario Pharmacists' Association be asked to establish formal mechanisms, at provincial and local levels, that will increase professional liaison, as necessary, on the issues of patient counselling and communication, as well as other issues of mutual concern. We suggest that emphasis be placed on liaison at the community level on an individual and group basis.**

In the common ambulatory care situation, when only the patient/prescriber and pharmacist are involved, it is highly desirable that there be agreement between prescriber and pharmacist as to who is doing what with regard to patient education. Proper use of the professional skills of pharmacists includes patient counselling about prescription and over-the-counter medication. The necessary patient education by the pharmacist will vary greatly according to circumstances. For proper teamwork, and the patient's best interest, there must be agreement to avoid duplication, potential confusion and the situation where each professional thinks the other has counselled the patient about the medication, when neither has.

In many situations it may be appropriate for the pharmacist to issue a drug information leaflet. Further, the Committee believes that local physician and pharmacist organizations could address this issue and agree on patient pharmacotherapy education in the community.

### 7.3 Hospital Formulary Committees

“The formulary is intended to improve the quality of drug therapy by restricting the prescribing choices to pharmaceutical preparations whose relative safety and efficacy have been judged superior to competing agents. Several studies have shown that the inclusion or deletion of a particular drug in to the hospital formulary is a major determinant of the use of drugs in a hospital (Hoffman, 1984 and Abramowitz, 1984.) For example, the removal of propoxyphene HCl from the formulary of a teaching hospital reduced its use from 40 per cent to less than 1 per cent (Hoffman, 1984.) Similar findings have been reported for other drugs (Huber et al, 1982 and Anandan, 1981.) However, a major study of formularies in 52 teaching hospitals in the USA found that the proportion of drugs included in the formularies, the relative safety

and efficacy of which were not up to standards, ranged from 9.3 to 69.7 per cent (Rucker and Visconti, 1978.) Lack of skills in comparative pharmacology and therapeutics on the part of physicians and pharmacists and the lack of feed-back from drug utilization studies, are given as major reasons for the inclusion of drugs into formularies that do not meet scientific requirements of efficacy and safety (Rucker and Visconti, 1979.)

"The inclusion or deletion of a drug from a formulary must be taken in the context of all other drugs included in the formulary. For example, gentamicin use increased after the deletion of cephalosporin in a hospital formulary (Reilly et al, 1978). Shifts in prescribing toward potentially more toxic and expensive drugs may result from an isolated restrictive measure (Plumridge et al, 1984). In summary, limiting drugs through a formulary may influence which drugs are given, but will not necessarily lead to a more rational approach to therapy (Harding et al, 1985)."<sup>28</sup>

The main discussion of the role of the hospital formulary committee is found in section 5.2, in conjunction with the hospital purchasing plans. But the effect of the hospital formulary committee is as much on prescribing practices as it is on acquisition of drugs for the practitioners within the institution. The committee is recommending guidelines that we hope will affect prescribing practices by establishing limited formularies and authorization requirements for prescriptions which do not fall within the formulary guidelines.

These guidelines are established for quality of care, as much as for budgetary reasons. Hospitals must make decisions with respect to what drugs to purchase within their global budgets. Until recently specific drug use in hospitals was not closely scrutinized but, with the very high cost of some of the newer drugs,

hospital formularies do take cost-effectiveness into consideration.

The Inquiry supports the establishment of guidelines for the appropriate use of high cost drugs (such as the new non-ionic radio contrast media and TPA). Another agent of special concern is erythropoietin, which will be used more in an out-patient environment. A review process is currently in progress to assess the financial impact of such an agent and to establish guidelines for its optimal use based upon the scientific literature. We support this process and believe that it might be expanded to include the participation of drug information pharmacists.

**7.19 The Committee therefore endorses the recommendation of the Task Force on the Use and Provision of Medical Services (Scott Task Force) to establish the Ontario Council on Health Technology Assessment, and recommends that as one of its tasks, that body evaluates new, high-cost drugs.**

Hospitals also use the expertise of their own staff to improve the prescription practices in the institution. This educational function is much more formalized in the major teaching hospitals, but the involvement of expert clinical pharmacists, physicians and nursing staff in recommending drug administration policies, through the pharmacy and therapeutics committees, is widespread.

The Inquiry encourages the involvement of professional staff in the ongoing task of improving prescribing patterns in their institutions. Where possible, such initiatives should also be extended to smaller institutions—including nursing homes and homes for the aged—as part of the development of local formularies and formulary committees as recommended in chapters 5 and 6.

<sup>28</sup> Carruthers, G., T. Goldberg, H. Segal & F. Sellers. *Drug Utilization: A Comprehensive Literature Review*. Ontario Ministry of Health, Toronto, Ontario, 1987, pp. 184-185.

## 7.4 Non-Prescription Medications

Drugs available in Ontario without prescription, sometimes referred to as “over-the-counter,” include many potent pharmaceutical entities. Examples are aspirin (ASA) and insulin. Many such drugs are important components of rational pharmacotherapy. The status of a particular chemical—whether it is categorized as a prescription, or non-prescription drug—is often as much an accident of history as a conscious decision to make the product subject to prescribing restrictions. In addition to useful qualities, all drugs have a potential for harm through adverse effects due to side effects, inappropriate dose, contra-indications and other factors. Therefore, the use of non-prescription products should be considered as carefully as the use of a prescription drug.

Many drugs available without a prescription fall in the category of “household, folk and traditional” remedies. As a result, consumers tend to see all the over-the-counter remedies in the same light—useful, but without potential for actual harm. The decision to self-medicate will often be part of ‘I’ll just try this and see if it helps’ thinking. Self medication with non-prescription drugs can, unfortunately, be a first step in illness behaviour rather than a welcome substitute for an unnecessary physician consultation. However, proper use of household and folk remedies for minor self limiting conditions is to be encouraged. There are many good and safe preparations available without prescription, and most consumers use these products in the correct manner—to alleviate symptoms in minor or self-limiting illnesses. But there are also situations where consumers use products imprudently, without knowing the implications of that use. And, as in all other areas, the highest levels of usage, and therefore the highest levels of misuse, are found in the elderly.

Many non-prescription preparations contain ingredients with the potential for harm as well as for benefit. It is, of course, necessary for prescribers to know which medications are being taken so that unwanted and potentially dangerous interactions can be avoided.

Stoller has summarized this situation well: “Even a carefully monitored program of drug therapy can be undermined by older patients’ use of over-the-counter medications. Self-medication also contributes to the risk of interactions, since patients rarely discuss over-the-counter drug use with their physicians. Uncontrolled and nondirected use of non-prescription drugs may also lead to toxicity, producing symptoms that in turn may be treated by additional drugs.

“A number of explanations have been offered for use of non-prescription drugs among the elderly. Use of these medications may be the first step in illness behaviour. Previous research has highlighted the importance of self-care in the management of illness, showing that the majority of symptoms are evaluated and treated outside the formal medical care delivery system.

“Bush and Rabin cited evidence that use of a non-prescription medicine is the initial response in almost half of all illness episodes, particularly for symptoms viewed as non-serious. Sharpe and colleagues argued that over-the-counter preparations may not be viewed as ‘real’ medicines and are probably used for minor or transient symptoms.

“Over-the-counter medications also may be viewed as a substitute for physician consultation. Palliative treatment of symptoms may seem preferable to professional consultation among elderly reluctant to admit to illness. Restricted access to medical care over the course of their lives may have generated greater reliance on self-treatment among current cohorts of elderly. Raffoul



suggested that this tendency to self-medicate may be reinforced by increased exposure to media advertisements of over-the-counter medications, exposures that he believes may increase with retirement. Furthermore, individuals who express scepticism regarding formal medical care and who believe that they understand their own health better than most professionals may be more likely to self-medicate with non-prescription drugs.

“In addition to relieving disease-related or stress-induced symptoms, self-medication may represent a direct strategy for coping with stressful situations. Lamy suggested that use of over-the-counter preparations or self-directed use of prescription drugs prescribed at another time may reinforce feelings of self-sufficiency among older patients.

“Not all older people use prescription and non-prescription medications with equal frequency, and researchers have identified a number of correlates to both types of drug use. For example, whites and women of all races were found to use both prescribed and over-the-counter medications more frequently than non-whites and men.

“Nonprescription drug use also has been associated with single person households and higher levels of education.”<sup>29</sup>

In chapter 8 a number of recommendations are made with the objective of encouraging increased participation of pharmacists in drug counselling for consumers. This includes the assumption of greater control and responsibility in the use of non-prescription drugs.

#### 7.4.1 Over-the-counter Drugs and Drug Benefit Programs

The decision to include or exclude prescribed over-the-counter medications as benefits under the ODB plan is contentious. If what is paid for by the plan is unrestricted, a wide variety of skin care preparations, laxatives, analgesics and vitamins come to be seen by beneficiaries as a right. They place pressure on physicians to have them “prescribed,” often to the irritation of the prescriber and dispenser, and at increased cost to the taxpayer. Many of these items are so-called “convenience” or “comfort” products. It can be argued that the money spent by the plan on these items would better be spent for needed items, and that consumers should pay for personal care products out-of-pocket.

Prescribers face the dilemma of either treating a patient unfairly by “denying” treatment that is potentially available as a free benefit, and which the patient desires, or pleasing the patient by prescribing the items and feeling guilty for possibly abusing the plan.

A proposed solution is the exclusion of all over-the-counter medications as benefits. This option has a number of negative consequences, the most important being the exclusion from the ODB plan of several important drugs. There is also substantial risk that the prescriber, acting out of concern for the patient or under pressure to provide a prescription, will substitute an expensive prescription drug for a less costly, but equally effective, non-prescription medication. In this way, making over-the-counter drugs “not a benefit” could actually increase overall plan costs.

<sup>29</sup> Palo Stoller, Eleanor, “Prescribed and Over-the-Counter Medicine Use by the Ambulatory Elderly,” *Medical Care*, 26:12 (1988) pp. 1149-1157.

A possible solution is to have these products under greater control by the dispenser. Recommendations and a discussion about this issue can be found in section 8.1. Many non-prescription medications (schedule C) are available in Ontario only with the consent of the pharmacist, and many others are available over-the-counter only in a pharmacy, and are theoretically under the indirect control of the pharmacist. This could provide a good opportunity for counselling by the pharmacist, although this now occurs all too rarely in practice. The Committee has recommended that pharmacists should exert more control over nonprescription medication, (recommendation 8.14) and that more information about the possible dangers of non-prescription medication use should be communicated to the consumer (recommendation 8.15.)

Another option is to establish a number of over-the-counter preparations as benefits, but to restrict the prescribing of them to specific indications. Balancing the benefit and harm of the possible solutions, the Committee has been convinced that prescription products should be dealt with in the same manner, whether the product can be sold without a prescription or not.

**7.20 The Committee therefore recommends that the DQTC be asked to review all the over-the-counter preparations that are currently benefits of the Ontario Drug Benefit plan in the same way that it reviews other prescription products, and that the over-the-counter preparations which are to be listed in the formulary be allocated to either the general or restricted use category.**



## Chapter VIII

### Dispensing/Administration

*This section dealing with dispensing was the subject of the Inquiry's fourth interim report. It deals with the two main responsibilities of the pharmacist, which are the cognitive, patient-oriented activities, such as consulting, and the product-related ones of acquiring, storing, labelling, packaging, dispensing and record keeping. Important recommendations deal with the restructuring of current pharmacy training.*

*The role of nurses is examined in terms of "nurse friendly" medical acquisition systems in long term care institutions, patient counselling, participation in pharmacy and therapeutics committees and ongoing continuing education, and problem solving mechanisms in case of disputes over propriety of treatment. Recommendations address these issues.*

*Other discussions and recommendations take into consideration hospital pharmacies, home care and outpatient services, hospital pharmacy residency programs and investigational drug use for clinical trials. The role of home care and other health care workers is dealt with from the perspective of the needs of caregivers and in light of the services available.*

#### 8.1 The Role of the Pharmacist

It should be noted that the majority of section 8.1, on the role of the pharmacist, was originally published in the Pharmaceutical Inquiry of Ontario's fourth interim report.

##### 8.1.1 Introduction

In discussing the dispensing of drugs, one of the major areas of our mandate, the Pharmaceutical Inquiry of Ontario determined that major changes were needed in the role of the profession of pharmacy. The contemplation of major changes in a professional role necessitated that we put forth certain ideas, and solicit responses to them, from the various pharmacy organizations. Therefore, on August 28, 1989, a discussion paper, which outlined positions on all points ultimately

addressed by the recommendations contained in the interim report, was circulated. Requests for comments were limited to individuals and groups in the practise of pharmacy and, although time constraints were stringent, we received a gratifying number of well-thought out responses.

While most of the comments focused on the topics covered in the paper, several included additional recommendations. Among these were requests, by the Ontario Hospital Association (OHA) and the Ontario branch of the Canadian Society of Hospital Pharmacists, to support more hospital pharmacy residency programs and, by the Ontario Pharmacists' Association (OPA) to adopt a dynamic formulary.

In general, the responses to our discussion paper, combined with input received



throughout the proceedings of the Inquiry, resulted in the recommendations concerning the profession of pharmacy in Ontario which follow.

### 8.1.2 Overview

Pharmacists' responsibilities for safe and effective drug therapy encompass both cognitive, patient-oriented functions and those which are distributive or product-oriented. The latter functions include acquiring, storing, labelling, packaging, and dispensing medication, as well as related record keeping. Patient-oriented activities involve consulting with prescribers, patients, and other health care professionals to optimize drug therapy.

It is our observation that the drug distribution system in Ontario is accessible, safe and reasonably efficient. The services of a pharmacist in a community or hospital pharmacy are, with a few exceptions, available in Ontario communities. Consumers are able to obtain necessary products with minimal delay or inconvenience, and the physical act of delivering drugs into the hands of the public is, generally speaking, carried out in a satisfactory manner.

However, pharmacists are not meeting their full potential as members of the health care team whose objective it is to ensure optimum drug therapy. We believe that ways must be found for pharmacists to provide more comprehensive patient-oriented services, including maintenance of medication and drug allergy profiles, monitoring of drug therapy, patient counselling, public drug education, provision of drug services to home care patients, drug utilization review programs, health promotion, self-care consultation services (non-prescription drug counselling, health care aids), and drug information and consultation services to other health care professionals.

The current economics of community pharmacy practice have a negative impact on the provision of patient oriented services and, in our view, are not in the public interest. The payment system, which is structured to reimburse pharmacies on the basis of drugs dispensed rather than professional services rendered, acts as a disincentive to the provision of certain desirable services. We believe that economic, professional and educational strategies must be developed to reward delivery of patient-oriented service while maintaining the product dispensing function.

### 8.1.3 Factors Leading to Change

The practice of pharmacy is subject to a rapidly changing environment. Public expectations, more elderly patients, government and other third-party involvement in the payment for drugs, human resource issues, new drugs, advancing technologies, professional expectations, and competency must all be considered when examining ways to improve pharmacy services.

**8.1.3.1. Public Expectations:** The public expect accurately and efficiently dispensed prescription drugs. They expect prescription and non-prescription drugs, health care aids and health related items to be available conveniently, in a timely manner, and at reasonable prices.

Less easy to define, but nonetheless vital, is the public expectation for patient-oriented services. A better informed public, more sophisticated in terms of drug use and health, is demanding more information from physicians, nurses, pharmacists and others. They want to know the reasons behind a particular drug therapy. They ask about drug dosage, administration, contraindications and alternative therapies.

**8.1.3.2. Patient Patterns—Demographics:**

While the birthrate is expected to level or decline slightly over the next decade, growth in the population aged 45 to 75 will accelerate, and older patients use more drugs. Immigration is leading to an increased need for labels and instructions in a variety of languages.

**8.1.3.3. Cost Containment:** It is generally recognized that if resources dedicated to the health care system continue to rise at the current rate there will be a very serious problem for our province. Expenditures for Ontario Drug Benefit (ODB) plan drug claims have increased from \$67.7 million in fiscal year 1976-77 to \$629.9 million in 1988-89,<sup>1</sup> and the number of eligible recipients, the number of approved drugs, utilization patterns, the dispensing fee level, and the cost of drug products in the formulary have increased significantly over this period. Along with those from government, there will be increased pressures from private insurance carriers and the public for cost containment measures.

**8.1.3.4 Human Resources:** The number of licensed pharmacists in Ontario has not been keeping pace with demand and both the community and hospital sectors have been reporting vacancies for several years. However, the human resource issue is complex and involves many factors in addition to a consideration of the simple demand situation, including the time spent by pharmacists on non-professional activities and the effective use of auxiliary personnel and technology. Other human resource related issues include the number of accredited pharmacies in relation to the need for pharmaceutical services in a particular community, the volume of prescriptions in these outlets, the expanded activities of pharmacists (unit dose dispensing systems,

increased counselling) and the effects of the increasing number of female pharmacists.

The proper deployment of non-professional personnel, such as pharmacy assistants, requires careful consideration. While pharmacists retain final responsibility for the drug dispensed or sold, the use of auxiliary personnel in this process has become significant. Such personnel can relieve the pharmacist of many of the technical or repetitive operations inherent in the product-oriented part of practice, freeing time for more patient-oriented tasks.

**8.1.3.5. New Drugs, Systems and Specialization:** The development of new drugs and delivery systems will challenge pharmacists to continue to expand their knowledge in the areas of pharmacology, therapeutics and pharmaceuticals. Growing fields of specialization—geriatrics, paediatrics, drug information, intravenous admixture, radiopharmacy, total parenteral nutrition—will also require new knowledge and the development of skills.

**8.1.3.6. Technology:** The advent of computers in pharmacy practice has had a significant positive effect on record keeping, preparation of labels, third-party billing and maintenance of patient medication histories, all functions which are now readily available in the computerized systems found in over 80 per cent of Ontario pharmacies. Drug interaction and information systems are developing very quickly, and these technological advances make pharmacists better equipped to dispense medication and provide appropriate analysis and intervention techniques. The advent of “smart cards” and centralized computer systems will further advance the capability of pharmacists to monitor drug therapy and intervene appropriately.

<sup>1</sup> Ontario Ministry of Health, Drug Benefit Utilization Summary Report, Service Data, 1976-77 and 1988-89.

Smart cards, which will concentrate an individual's drug history into a single record, represent a significant step forward. But they are, after all, simply a record. To benefit a patient in terms of choice of therapy, avoidance of untoward reactions, and proper drug utilization, there must be a reference to this record by the pharmacist and the prescriber (a physician or dentist) with subsequent interaction among the pharmacist, prescriber and patient. In the case of the two health care professionals, this may involve a centralized interactive computer system.

Original packaging dispensing, as commonly practised in Europe, introduces another dimension to pharmacy practice. This technology, coupled with computerized labelling and automated dispensing, could lead to a dramatic change in the activities of pharmacists away from the distributive function toward the cognitive one.

**8.1.3.7. Professional Expectations:** As pharmacy students become more highly trained in patient-oriented practice and clinical pharmacy, their expectations will shift from a product orientation to a more patient-oriented type of practice.

In addition, the expectations of other health care professionals will increase with respect to the contribution that pharmacists can make toward rational drug therapy.

**8.1.3.8. Competence:** While efforts will continue in the area of quality assurance in drug distribution, competence assurance is fast becoming an issue in terms of professional service and licensing requirements. In future, increasing emphasis on the cognitive aspects and on patient-oriented practice will lead to greater involvement in developing and monitoring drug therapies.

## 8.1.4 Issues and Recommendations

The issues identified in the following discussion are based on various product and patient-oriented responsibilities of pharmacists. The issues related to human resources and education overlap both patient and product responsibilities.

**8.1.4.1 Product-Oriented Responsibilities:** Product-oriented responsibilities of pharmacists relate to the evaluation and dispensing of prescriptions and sale of non-prescription drugs. The pharmacist interprets and evaluates prescriptions for correctness and completeness, verifies authenticity and appropriateness, and determines urgency. Prescription preparation involves the selection of the appropriate product and ensuring that it is dispensed in accordance with requirements of the prescriber, the needs of the patient, and legal considerations.

Auxiliary personnel (variously called pharmacy assistants, dispensary assistants, pharmacy technicians) are widely used to carry out certain functions related to the process. Generally speaking, they perform in a reasonable and effective manner, although there is room for improvement. There appears to be a certain amount of undesirable "role reversal" with some pharmacists carrying out physical acts of dispensing, while leaving assistants to deal with patients. Clearly, the assistant should concentrate on product-oriented tasks, freeing the pharmacist for patient counselling and similar professional functions.

**8.1** The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists clearly defines the respective roles of auxiliary personnel and pharmacists and ensures that assistants perform technical, product-oriented tasks while pharmacists concentrate on patient oriented tasks such as monitoring drug therapy and providing advice on drugs to



**patients and other health care professionals. The strategies used to ensure this implementation should be associated with the promulgation of standards of practice and competence assurance.**

While the respondents to our August 1989 discussion paper generally supported the establishment of standards for auxiliary personnel, the OHA made a recommendation to further study the issue. The OPA suggested that standards for training these individuals for positions in community pharmacies are not necessary.

Pharmacists can also maximize the effective use of professional time by the increased use of computers. Because computer use is tied closely to the billing procedures of the Ministry of Health (MOH), development of new programs often involves considerable input by the Ministry. It is vital that the time saved by the increased use of computers be utilized by pharmacists in a professionally-oriented fashion, such as patient consultation, and that aids to patient consultation contained within the computer programs be accessed by the pharmacist and not just by the assistant.

**8.2 The Committee therefore recommends that, by the end of 1992, the Ministry of Health, the Ontario College of Pharmacists and the Ontario Pharmacists' Association jointly devise requirements for information management systems, and guidelines for their use, which will ensure optimal access to patient profiles, and adverse drug interaction programs. In addition, the Committee recommends that the Ontario College of Pharmacists establish practice guidelines to implement the optimal use of this type of information management system.**

In Canada the majority of unit dosage form prescription drugs dispensed are transferred from a bulk container to child resistant packages for delivery to the patient. Original

packaging dispensing, common in Europe, is emerging. This is due primarily to initiatives by brand name manufacturers and is likely to escalate. While this form of packaging has many advantages, it should not lead to uncertainty or confusion, be a hindrance to individualized treatment regimens, impede interchangeability of drug products, or be a marketing or promotional tool.

**8.3 The Committee therefore recommends that, by the end of 1990, standards be established for pharmaceuticals introduced in what is known as "dispensing size" or "original pack" packages. The standards should ensure that no original package dispensed should create uncertainty or confusion, be a hindrance to individualized treatment regimens, impede interchangeability of drug products (for purposes of interchangeability, physical characteristics of packages should not be regarded as unique) or be a marketing or promotional tool (promotion to the public of a particular brand should not be a feature of design or labelling.) In addition, the packages should be required to meet child resistant standards.**

**8.4 The Committee further recommends that the Ministry of Health, in consultation with appropriate interested organizations, promptly undertake discussions with the Health Protection Branch of Health and Welfare Canada to establish these standards.**

At present, the majority of patients view pharmaceutical services primarily as product-oriented. The emphasis is on the essentials of the dispensing function: the correct drug, in the proper strength, dosage form and quantity, along with instructions for use. However, the patient may not be aware of special instructions for taking the drug properly, contraindications, or other precautions, and may not comprehend or be able to read the instructions. It is in this area

of communicating with the patient that improvements can be made. For the ambulatory patient, these improvements can take the form of better designed labels, use of auxiliary labels, use of printed inserts, and verbal reinforcement, which is especially important when a patient receives a particular prescription for the first time.

**8.5 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists establish a working group for the express purpose of expanding the practise of providing auxiliary labels and other printed information on prescription drugs, along with verbal reinforcement to the patient by the pharmacist. The working group should include consumer representation.**

Various patient groups have special communication needs. With respect to visually handicapped individuals, we are aware of programs that have been developed and feel that these programs should be encouraged.

**8.6 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists encourage the profession to pay particular attention to the needs of visually handicapped patients by using large type, and appropriate inserts and graphics whenever possible, in the preparation of prescription labelling.**

Other patient groups with special communication needs are those whose language is not English or French.

**8.7 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists encourage the use of labels and other directions in the language familiar to the patient, with the pharmacist providing appropriate verbal reinforcement.**

#### **8.1.4.2 Patient-Oriented Responsibilities:**

Patient-oriented responsibilities include monitoring drug therapy, counselling patients and providing drug information to other health care professionals and the public.

Pharmacists have been regarded as a "second line of defence" in drug therapy. Ideally, the pharmacist maintains a complete patient medication profile. When a prescription is received, the pharmacist assesses prescribed medication in the light of the profile and other factors, contacts the prescriber if necessary, and monitors compliance. In addition, a pharmacist is in the best position to review the non-prescription drug use of patients.

Monitoring drug therapy involves knowing what drugs the patient uses and intervening when appropriate. Factors to be considered include: potential allergies, sensitivities or side effects; potential for certain indications; possible interactions of drugs with other prescribed drugs, non-prescription drugs, foods, and diseases; possible drug duplication, multiple prescribing, excessive use and drug abuse; degree of compliance with prescriber regimen; effectiveness of drug therapy; and adverse drug reactions. There remains the vital requirement of increased communication among the patient, nurse, prescriber and pharmacist. In order to improve just one of these communication links, and to increase the application of patient profiles, the pharmacist/patient relationship needs to be regularised as much as possible.

**8.8 The Committee therefore recommends that, by the end of 1990, the Ministry of Health conduct an education campaign, directed primarily at seniors, recommending that patients select a pharmacy and, in so far as this is practical, obtain all pharmacy services there.**

In order to monitor effectively, the pharmacist must possess information on the complete drug regimen of the patient, including both

prescribed and non-prescription medication. The vast majority of Ontario pharmacies already maintain patient medication profiles on a voluntary basis.

**8.9 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists enforce this voluntary trend through regulations requiring all pharmacies to maintain patient medication profiles in compliance with defined content standards.**

General support for this recommendation was expressed in response to the August, 1989 discussion paper, although the OPA preferred to see the requirement encouraged rather than mandated.

In addition to patient medication profiles maintained by pharmacists, there has been significant development in the use of portable patient drug profile records. If properly maintained, these records will assist in providing more complete information to pharmacists on drug therapy for particular patients.

**8.10 The Committee therefore recommends that the Ontario College of Pharmacists, the Ontario Pharmacists' Association, the Ministry of Health and other interested parties diligently pursue the development of portable patient medication records such as the "smart card."**

While the portable patient medication record is a useful tool for drug therapy monitoring, we regard this only as an interim step. In order to realize the full potential of the pharmacist as a participant in the patient's drug therapy, a more interactive and consistent form of communication between the patient, pharmacist and prescriber is indicated. In order for pharmacists to maximize their role in patient and prescriber consultation, pharmacists must have access to the complete drug regimen of the patient, and know the condition(s) being treated.

**8.11 The Committee therefore recommends that, by the end of 1990, the Ontario Medical Association, the College of Physicians and Surgeons of Ontario, the Royal College of Dental Surgeons of Ontario, the Ontario Pharmacists' Association, and the Ontario College of Pharmacists devise guidelines to ensure that the pharmacist, when clinically appropriate and with the agreement of the patient, has access to the patient's diagnosis(es.)**

After determining the level of communication appropriate for each patient, pharmacists provide the necessary verbal, written and pictorial information in an effort to optimise drug use. Information on indications, dosage frequency, directions, storage, appropriate action for misdoses, signs and symptoms of therapeutic response (or failure), compliance, advice on aids for compliance, as well as the potential for interactions, is provided. From a purely practical point of view, the pharmacist also discusses with the patient the refill directions of the prescriber and the necessity for checking back with the prescriber for a further supply of medication.

These functions are included in the professional services provided by pharmacists; they should be prompted by ethical and practice standards, not by law. The pharmacist is reasonably well trained to perform these functions (although improvements can be made) and the extent to which such counselling is done needs to be increased. Members of the public are not always fully aware of these services, and for this and other reasons, such as lack of interest, time, shyness, desire for privacy, language or other communication barriers, often do not request the optimum level of service. We are convinced that a more informed public, asking questions about medication, will result in an increase in the provision of these services by pharmacists.



A public education program, focusing on the services that patients can expect to receive from pharmacists, will create heightened awareness of the importance of proper drug use, and improved compliance with drug regimens.

**8.12 The Committee therefore recommends that, by the end of 1990, the Ministry of Health, in co-operation with appropriate interested organizations such as the Ontario Pharmacists' Association and the Ontario College of Pharmacists, launch a campaign to make the public more aware of the services that can be expected of a pharmacist, with emphasis on those related to the provision of information on the proper use of medications.**

One of the barriers to effective communication between pharmacists and the public when prescriptions are presented, or non-prescription drugs sold, is the physical lay-out of pharmacies. We believe that pharmacies should have an area permitting reasonably private discussion between patient and pharmacist.

**8.13 The Committee therefore recommends that the Ontario College of Pharmacists require all pharmacies in Ontario, by the end of 1991, to have an appropriate consultation area where patients can discuss their medication with a pharmacist, in privacy and relative comfort.**

**8.14 The Committee also recommends that pharmacists exercise more personal control over the sale of non-prescription drugs and that, by the end of 1991, the Ontario College of Pharmacists require all pharmacies in Ontario to have a professional products area, adjacent to or contiguous with the dispensary, where all non-prescription drugs—with the exception of Schedule "C" drugs which must not be available for self-selection—must be located.**

This recommendation was also generally supported by the respondents to the discussion paper, although the OPA again stated that it preferred to encourage rather than mandate this development.

The drugs in this contiguous area would be under more vigorous supervision by the pharmacist than the non-drug products available generally in the front shop. In order to further assist the pharmacist to exercise the control suggested in the previous recommendation, steps should be taken to alert the public to the importance of consulting a pharmacist regarding the use of non-prescription drugs, particularly when these are taken concurrently with prescription drugs.

**8.15 The Committee therefore recommends that, by the end of 1991, the Ontario College of Pharmacists require the use of signs and printed material within the pharmacy to alert the public to the importance of consulting a pharmacist regarding the use of non-prescription drugs, especially when these are taken concurrently with prescription drugs.**

Pharmacists in community practice derive their professional income directly (owners) or indirectly (employees) from the sale of prescription and non-prescription drugs. While it is true that professional services can be (and are) reimbursed by way of professional fees, and a mark-up on drug products, it is obvious that income is maximized by increased sales of both categories of drugs. Mechanisms should be investigated which would reward the provider of professional pharmaceutical services, whether or not a drug is sold or dispensed.

Proposals for innovations in the method of reimbursement for pharmacy services, perhaps involving pilot projects or other experimental approaches, need to be tested and developed. Alternative remuneration

systems for providing professional services would not be linked directly to the sale of a drug. One objective of such an endeavour would be to heighten awareness among other health care professionals and members of the public of the scope and value of pharmacy services.

**8.16 The Committee therefore recommends that, by the end of 1991, the Ministry of Health, in cooperation with the Ontario Pharmacists' Association, establish pilot projects to examine and assess alternative reimbursement and payment mechanisms which would reward the provider of professional pharmaceutical services and be independent of the sale or dispensing of a drug.**

One such mechanism is fee for service on a per capita basis in an environment such as a nursing home, home for the aged or comprehensive health organization. Another example is the payment of a fee when the pharmacist, upon receipt of a prescription and with the agreement of the prescriber, either changes a drug therapy, or eliminates the drug entirely.

Prescriptions in Ontario are paid directly by the public, by the ODB plan, or by a third-party insurance plan. If patient-oriented services are to be encouraged, a form of reimbursement needs to be identified and the services themselves must be visible and obvious to the public.

Optimum patient care includes continuity of care, and requires complete knowledge of a patient's medications by both the hospital and community pharmacist, as well as communication between these parties.

**8.17 The Committee therefore recommends that, by the end of 1992, the Ministry of Health, in conjunction with the Ontario Pharmacists' Association, the Ontario College of Pharmacists and the Ontario Hospital Association, create a linkage**

**between patient medication files in community and hospital pharmacies and ensure that pre-hospitalization or discharge consultations stress the importance to the patient of such an exchange of information.**

While the ultimate goal of both community and hospital pharmacy practice is optimal drug therapy for the patient, the differences in practice environment and payment mechanisms between pharmacists operating in one or the other milieu must be recognized. For example, pharmacists in hospital practice have more opportunities than their community based colleagues to become involved in certain activities, such as pharmacotherapy consultation and therapeutic intervention programs. All pharmacists, whether hospital or community based, should be encouraged to become involved in these types of professional activities to the extent possible.

The trend to increasing use of formularies should be encouraged and the potential contribution from the clinical expertise of pharmacists must be more fully utilized. Studies of pharmacy programs providing pharmacotherapy consultation, drug therapy monitoring, and subsequent intervention when necessary, have been examined in the institutional setting and have proven effective in improving quality of care and reducing cost.

**8.18 The Committee therefore recommends that the Ministry of Health, in conjunction with the Ontario Hospital Association, the Ontario Medical Association, the Ontario Pharmacists' Association, the Canadian Society of Hospital Pharmacists (Ontario branch), and the Ontario College of Pharmacists immediately encourage the expansion of the clinical role of pharmacists in the increased use of formularies, pharmacotherapy consultation, drug therapy monitoring and subsequent intervention when necessary.**

The pharmacologic consulting role of the pharmacist in monitoring the use of potentially toxic drugs through the evaluation of response and drug concentrations and end-organ effects is recognized and should be expanded. While there are practical limitations, the potential for expansion into community practice sites should be explored.

Therapeutic intervention programs are those initiated by a pharmacist to effect a change in a patient's drug therapy. An intervention is accepted by a prescriber if it results in a change to the drug order or prescription in question. Drug therapy monitoring and subsequent intervention when necessary is an essential component of pharmacy services and should be encouraged both in hospital and community practice. The Committee is convinced that the increasing use of formularies, pharmacotherapy consultation, drug therapy monitoring, and subsequent intervention when necessary, can and should be an essential component of pharmacy services in community and hospital practice, nursing homes, homes for the aged and other institutions.

**8.19 The Committee therefore recommends that, by the end of 1992, the ministries of Health and Community and Social Services, in cooperation with the Ontario Medical Association, the Ontario Nursing Home Association, the Ontario Association of Non-Profit Homes and Services for Seniors, the Ontario Pharmacists' Association and the Ontario College of Pharmacists, set up pilot projects which involve community drug therapy committees based on models existing in institutional settings.**

To provide direct input into the prescribing practices of physicians and other prescribers, pharmacists must have ready access to drug information. This will also allow them to deal with questions and problems at the patient level, assist with the development of drug formularies, and become generally more

knowledgeable. Pharmacists currently have access to a variety of sources of information, including the traditional textbooks, journals, and other sources such as tapes, videos, and seminars, as well as to several drug information services. One such service is operated by the Ontario College of Pharmacists and is located at the faculty of pharmacy, University of Toronto; others are located in hospitals. These are useful services which could be expanded and co-ordinated for better utilization of expertise.

**8.20 The Committee therefore recommends that, by the end of 1990, the Ministry of Health and the Ontario College of Pharmacists ensure that drug information programs are encouraged, supported, coordinated and expanded to other professionals.**

#### **8.1.4.3 Human Resources and Education:**

To achieve the desired level of pharmaceutical services, there must be an adequate supply of properly educated personnel. For this reason, we believe that human resource and education issues touch on the product-and patient-oriented aspect of pharmacists' responsibilities dealt with in the previous discussion.

Some human resource related issues have been discussed earlier. This section examines "demand" versus "need" for pharmacists and makes recommendations regarding the training of pharmacists.

During the period 1981 to 1988 there was a 19.5 per cent increase in the number of community pharmacies in Ontario (from 1,737 to 2,076). It should be noted that there has also been an increase in prescription volume during this period. The number of pharmacists licensed to practice in our province during the period 1981 to 1988 rose by 23.9 per cent (from 5,815 to 7,206). Graduates from the faculty of pharmacy, at the University of Toronto (the only pharmacy faculty in Ontario) accounted for



approximately 65 per cent of the newly licensed pharmacists in 1981. In 1988, this figure had dropped to 42 per cent. The rest of Canada accounted for 16 per cent of the new licensees in 1981, and 24 per cent in 1988, with other countries contributing 19 per cent in 1981 and 34 per cent in 1988. The number graduating from the University of Toronto has remained relatively constant during this period with those coming from other jurisdictions gradually increasing. (see table 8.1)

Table 8.1

**Sources of Pharmacists  
Ontario 1981 to 1988**

Year	U of T	Other provinces	Other countries
1981	65%	16%	19%
1985	51%	21%	28%
1986	43%	23%	34%
1988	42%	24%	34%

Source: Ontario College of Pharmacists

It appears that the situation existing for many years in some provinces, where the numbers graduated exceeded opportunities for practice, has now changed. The number of pharmacists coming to Ontario from other provinces has levelled off in the past two years while those from other countries has increased.

There is vigorous competition between those seeking to employ pharmacists for community and hospital practice and among employers within these sectors. Metropolitan and larger urban centres are more attractive to a majority of pharmacists seeking employment than are rural or more remote communities. It has been argued that the larger centres are over-served with pharmacies in some cases while some small or remote communities may have no pharmacy, or the local pharmacy may be experiencing professional staff shortages.

There is undoubtedly a continuing demand for pharmacists in Ontario. What is imponderable is the actual need. The Inquiry is not aware of research or data that has determined need for pharmacists on the basis of any measurable factor such as optimum number of pharmacists per capita, number of prescriptions dispensed, or any other variable.

Resolution of the demand versus the need for pharmacists issue will not be possible unless controls are placed on demand, since it seems unlikely (and indeed perhaps not desirable) in our system to limit the number of pharmacies. We must attempt to meet demand for pharmacists as realistically as possible.

What is clear to the Inquiry is that at present, Ontario suffers from a shortage of pharmacists with an adequate clinical orientation. It is our opinion that this shortage can best be addressed through training additional pharmacists within our own province. This training should be based on educational goals and objectives that have been derived from a careful consideration of the enhanced clinical orientation of the pharmacists as recommended elsewhere in this report.

The faculty of pharmacy at the University of Toronto is overcrowded and understaffed. As mentioned above, it now contributes fewer than 50 per cent of the pharmacists licensed each year in Ontario, despite an enrolment which exceeds, by approximately 30 per cent, that for which it was designed.

**8.21 The Committee therefore recommends that, by the 1992 academic year, or the year a new faculty of pharmacy starts operations (see recommendation 8.22), the faculty of pharmacy, University of Toronto, reduce its enrolment to the level for which it was designed.**

The Committee strongly supports the establishment of a second Ontario faculty of pharmacy. The Committee is persuaded that

the study of pharmacy is best undertaken in association with the facilities of a medical school and, mindful of needs and opportunities for education in northern Ontario, supports the establishment of a second faculty of pharmacy at a northern Ontario university, provided a health science program that includes a faculty of medicine is established there. If this is not likely during the next three years, a second faculty of pharmacy should be established at an Ontario university that already has a faculty of medicine.

**8.22 The Committee therefore recommends that, by the 1992 academic year, the Ministry of Colleges and Universities establish a second faculty of pharmacy in Ontario, with an enrolment approximating the reduced level of the Toronto faculty. This should be a five year program similar to that recommended for the University of Toronto (see recommendation 8.23), established at an Ontario university that has a health sciences program which includes medicine. The decision to establish this faculty should take into consideration the need for such services in northern Ontario, but the Committee believes the advantages of having faculties of both medicine and pharmacy at the same location outweigh geographic concerns.**

While the Committee acknowledges that the undergraduate program is becoming more clinically oriented, there is room for improvement and the trend towards increased emphasis on training for patient-oriented practice (communications, patient counselling, therapeutics, drug information, pathophysiology and geriatrics) should be encouraged. There is also a need for a more effective reinforcement, in a practical setting, of the undergraduate course material and for establishment of patient-oriented role models for students.

**8.23 The Committee therefore recommends that, by the 1991 academic year, the**

**University of Toronto embark on a five year undergraduate pharmacy program to permit more structured practical training and increased instruction in communications, patient counselling, therapeutics, drug information, pathophysiology and geriatrics.**

Practical training for licensure in Ontario is conducted in community and hospital pharmacies under a semi-structured system. Few requirements are made, either by preceptors or the training environment. While this system provides pharmacy students with summer jobs and practical experience, it has definite shortcomings from an educational perspective.

**8.24 The Committee therefore recommends that the practical training program for pharmacy students and interns be structured and form part of the five year program recommended above (see recommendation 8.23.)**

More pharmacists with a doctor of pharmacy degree are needed to assume teaching, research, practice and leadership roles. At present, students wishing to pursue this degree program must do so in the U.S. or Europe and the costs make this inequitable.

**8.25 The Committee therefore recommends to the Ministry of Colleges and Universities that, within the next two years, a doctor of pharmacy program be established at an appropriate faculty of pharmacy at an Ontario university.**

Prescribers need a greater understanding of the contributions that can be made by pharmacists. At the undergraduate or immediate post graduate level, there should be a collaborative effort between the faculties of medicine and pharmacy to jointly instruct students through undergraduate courses and internship programs. Areas such as choice of drug therapy, monitoring techniques and

patient counselling would be covered. The purpose would not be to train both groups to do the same thing, but to instill the notion of the unique, but collaborative, contribution each can make to the patient's drug therapy.

**8.26 The Committee therefore recommends that, by the 1991 academic year, the faculties of medicine and pharmacy at the University of Toronto jointly instruct students in patient-oriented services, including choice of drug therapy, monitoring techniques and patient counselling. This recommendation is also directed to the Ministry of Colleges and Universities and the Council of Ontario Faculties of Medicine as a requirement for the establishment of an additional faculty of pharmacy.**

There are serious professional human resource deficiencies in some rural communities, and especially in northern Ontario where the shortage of pharmacists, as well as other professionals, threatens the provision of optimal health services, including rational drug therapy.

A promising strategy to address this problem is to train undergraduate and post-graduate students in communities removed from the large southern Ontario centres. Accordingly, the committee favours the establishment, or expansion where they already exist, of training posts in rural or northern Ontario.

**8.27 The Committee therefore recommends that the Ministry of Colleges and Universities reach an early decision regarding the planning of such a health science centre in northern Ontario.**

The growing fields of specialization such as geriatrics, paediatrics, drug information, intravenous admixture, radiopharmacy and total parenteral nutrition will also require the development of new knowledge and skills.

**8.28 The Committee therefore recommends that, by the end of 1991, the faculty of pharmacy, University of Toronto, review its curriculum with a view to increasing the emphasis in communications, patient counselling, therapeutics, drug information, pathophysiology and geriatrics. At the same time, the Ontario College of Pharmacists should review its requirements for continuing education to include courses in pharmacology related to geriatrics and paediatrics, as well as courses in drug information, intravenous admixture, radiopharmacy and total parenteral nutrition.**

In the earlier section on product-related responsibilities, reference was made to the need for a public education program to create heightened awareness of the importance of proper drug use. A corollary to that deals with the need to train medical personnel to communicate effectively with patients on that topic.

**8.29 The Committee therefore recommends that, by the 1991 academic year, the University of Toronto and the Council of Ontario Universities' Health Science Faculties ensure that training for medical, nursing and pharmacy students include appropriate emphasis on the need to communicate to the patient the importance of proper drug use.**

## **8.2 Role of the Nurse**

### **8.2.1 Use of Human Resources**

Optimal use of all human resources is clearly desirable, and this is especially so in areas where there are shortages. Human resources must also be considered within a larger context encompassing all the relevant disciplines, because system changes for one profession inevitably affect the others. Medication



acquisition systems in long term care institutions must clearly be “nurse friendly” and must not needlessly take up nursing time.

Within this framework, the unit dose system of dispensing (see recommendation 6.8) has many advantages, including great savings in nursing time and efficiency. Because much of the work can be done by pharmacy assistants, it makes sense to spend extra money on a carded bubble package or unit dose system. The institutions gain in terms of the nursing time saved, and the extra overall cost is small. The Committee believes that similar efficiencies can be realized in other areas.

**8.30 The Committee therefore recommends that, by 1991, the Ministry of Health, together with the Ontario Hospital Association, the Ontario Association of Non Profit Homes and Services for Seniors and the Ontario Nursing Home Association, review and improve as necessary, medication acquisition, storage, dispensing and administration systems in long term care institutions.**

### 8.2.2 Counselling

Although responsibility for administering medication in hospitals and institutions usually falls to the nurse, it is currently unclear to what extent nurses should be counselling clients with respect to medication. Lack of compliance to medication regimens has been well documented. This can lead to lack of resolution of the diagnosed condition and possibly deterioration—results which can cause increased stress to the patient as well as the system.

Of all health care providers, nurses frequently have the most regular contact with the patient, allowing them the greatest influence on patient compliance. Nurses in institutions, clinics, physicians’ offices and community health could be directed to be more proactive

in educating patients with respect to medication regimens, and means of compliance. In addition, in the compliance-enhancing role, the extent to which nurses should be advocates for patients is unclear. Standards and policy should be developed to clarify the extent to which nurses should act as advocates with respect to problems such as discussion of adverse effects, side effects and alternatives to drug therapy.

**8.31 The Committee therefore recommends that an interdisciplinary committee of the College of Nurses of Ontario, College of Physicians and Surgeons of Ontario and the Ontario College of Pharmacists should be established to determine the appropriate role of the nursing profession in patient counselling.**

Due to their close contact with patients, nurses are not only in a unique position to improve compliance but also to view the effects and adverse effects of the medications and provide valuable information for various committees reviewing the effects of drugs.

**8.32 The Committee therefore recommends nursing participation in drug utilization review, pharmacy and therapeutics committees.**

### 8.2.3 Education

Following these objectives, educational bodies should establish curricula to reflect these decisions. A “Choice of Medications—1990” publication, the *Compendium of Pharmaceutical Specialties*, and drug information leaflets will help, but specific continuing education directed at this responsibility is probably needed. Clearly it is important to convey the message that on-going educational opportunities must be made available for nurses.

**8.33 The Committee therefore recommends that:**

- a) **There be more continuing education for nurses regarding optimal pharmacotherapy; and**
- b) **The College of Nurses of Ontario be asked to re-examine the nursing curriculum to ensure that a sufficient knowledge of basic therapeutics is included to allow meaningful postgraduate study and experience to make the nurse an effective treatment counsellor.**

Particularly in the current human resource shortage situation in the nursing profession, there may often be a lack of time during scheduled shifts to participate in continuing education. Health care professionals accept the responsibility of keeping up to date; it is a part of being a professional. However, it can be very difficult for those on salary to maintain competence and expand their knowledge base. Employers should recognize these problems and budget to allow adequate participation and ongoing education. In practice, the employer of the majority of health care professionals in Ontario, directly or indirectly, is now the government. Increased support for post graduate education about pharmacotherapy could well be a "good buy" for the province, both in terms of improved treatment for citizens and by promoting rational pharmacotherapy, which may well save money.

**8.34 The Committee therefore recommends that:**

- a) **The College of Nurses of Ontario clarify and establish standards for basic and continuing education about pharmacotherapy; and**
- b) **The Ministry of Health budget sufficient funds to its health care organizations to allow them to fund nurses' participation in ongoing education (i.e. paying the cost of education.)**

Nurses should expect to spend some unpaid time on these endeavors, but health care budgets should be sufficient to remunerate nurses for the acquisition of at least part of this necessary knowledge base. (i.e. paying nurses to be further educated.) Government/nurse negotiations should clarify this issue.

Nurses should be one of the professional groups toward which the drug information program is directed, as recommended earlier.

#### **8.2.4 Institutions**

In accredited hospitals, a mechanism always exists for dealing with physician/pharmacist/nurse disagreements about pharmacotherapy. Most such problems are dealt with in the ordinary discussions that are part of the proper teamwork so essential in modern therapeutics. However, the very existence of a formal dispute settling mechanism may well minimize the need for implementing it. It is important that nurses should always have access to a line of appeal if asked to participate in treatment they do not believe to be in the patient's best interest.

Problems arise when a medication is prescribed that is contraindicated under certain circumstances, which in the opinion of the nurse, seem to apply to the patient in question. Of course most contraindications are relative and it may be that the prescriber considers the balance of risk favourable and has failed to adequately communicate that line of reasoning to the nurse expected to administer the medication. Sometimes, however, the prescriber is not aware of the contraindication and communication from the nurse is in the patient's best interest. There seems no doubt that nurses should not administer a medication which, they believe, will do more harm than good. Both support from superiors and a suitable problem solving procedure must be available to any nurse administering medication.

We believe that such mechanisms may not always be available at present.

The pharmacotherapy knowledge base required by a health care professional may vary tremendously but basic principles are clearly important to all. The role of nurses as treatment counsellors seems likely to steadily increase in many areas (eg. mental health, diabetes and intensive care.)

**8.35 The Committee therefore recommends that any organization employing a nurse who administers medication should ensure that a suitable problem-solving mechanism is available in case of dispute over the propriety of treatment.**

The discharge of patients from institutions to continue treatment at home is always important. Proper patient care, as well as conservation of health care resources, demands that proper patient education occur prior to and during the discharge process. Without such education, compliance can be expected to be less, treatment failure may occur, and expensive readmission may follow. The nurse is often especially well placed to make sure that a medication list is prepared, appropriate follow up is arranged and the patient and/or relatives understand what is advised. The prescriber's role remains pivotal and in some cases a pharmacist may perform this service. But overall, at present and for the foreseeable future in Ontario, it will be nurses who implement discharge procedures.

**8.36 The Committee therefore recommends that, in all health care institutions in Ontario, mechanisms be put in place to ensure appropriate patient education regarding treatment plans prior to discharge. Adequate time must be budgeted to allow for this and if it is to be done by nurses then adequate resources must be**

**available to assure the nurse appropriate and ongoing education about pharmacotherapy issues.**

### 8.3 Hospital Pharmacy

The description of the manner in which dispensing is carried out at the hospital level is taken mainly from information provided by the OHA in its submissions to the Inquiry.<sup>2</sup> Initially, the dispensing function includes review of the medication order. Other considerations are the appropriateness of the chemical entity, the required dosage, strength, frequency and route, and duration of administration. The expertise of the pharmacist is called upon to assess these elements of the medication order in the light of what is known about medications and about the patient, the diagnosis, other medications, allergies and previous therapies. Evidently, not all hospital pharmacists have access to patient profiles. As the requirement for maintenance of patient profiles in community settings has been recognized, it is equally necessary for patient care in the hospital environment.

**8.37 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists, the Ontario Branch of the Canadian Society of Hospital Pharmacists and the Ontario Hospital Association take steps to ensure that all hospital pharmacies require patient medication profiles in compliance with defined content standards.**

One of the major pharmacy controls for drugs in hospitals is the hospital formulary concept, which was discussed in section 7.3. Medication orders for non-formulary products will only be filled (because they are not normally stocked) and dispensed if the prescriber

<sup>2</sup> Briefs #57-5100 and 57B-5100.



complies with the institution's requirements for non-formulary products. Automatic stop orders for certain classes of drugs also add prescribing controls; in order for a drug to continue past a certain number of days or repeats, the physician must personally review and renew the order. In addition, under defined circumstances, pharmacy departments should be able to automatically change the frequency and dosage of certain medication orders to comply with recognized standards.

### 8.3.1 Out-patient Services

A number of problems associated with the provision of services to out-patients in hospitals have been drawn to the attention of the Inquiry. These include the professional fee paid to the hospital under the ODB plan, high-cost new drug programs and investigational drug use for clinical trials.

Several Ontario hospitals dispense prescriptions to out-patients; in the case of drug benefit recipients, they are reimbursed at half the professional fee currently allowed for community pharmacies. Issues surrounding this question include drug acquisition costs for hospital out-patient dispensaries and funding for staff, facilities and other resources.

**8.38 The Committee therefore recommends that the Ministry of Health and the Ontario Hospital Association review the rationale behind the reimbursement policy for Ontario Drug Benefit prescriptions dispensed for hospital outpatients.**

Various high cost drug programs are currently being operated through hospitals. These include drugs for cystic fibrosis, thalassaemia and AIDS patients (AZT and pentamidine). It has been drawn to the attention of the Inquiry that the approach taken by the Ministry of Health to the funding of these programs may have the effect of compromising patient care services.

**8.39 The Committee therefore recommends that by 1991, the Ministry of Health, in cooperation with the Ontario Hospital Association, establish mechanisms to adequately compensate hospitals providing professional pharmacy services to out-patients.**

### 8.3.2 Home Care Services

The Inquiry supports efforts to reduce the length of hospital stay for patients where clinically appropriate. One way this can be done is through the establishment of programs which permit drugs otherwise administered in institutions to be administered in the home. While we are aware that such programs are available now, we feel they should be encouraged and expanded through specific incentive programs.

**8.40 The Committee therefore recommends that total parenteral nutrition, intravenous antibiotic, analgesic and other home care drug programs be enhanced and expanded through an incentive reimbursement program to be negotiated by 1991 by the Ministry of Health, the Ontario Hospital Association, the Ontario Pharmacists' Association and other interested parties.**

### 8.3.3 Hospital Pharmacy Residency Programs

One-year post-graduate pharmacy residency programs affiliated with the University of Toronto provide additional training in hospital pharmacy practice. It has been drawn to the attention of the Inquiry that attracting candidates for these programs is becoming more difficult due to the limited stipend. In view of the need for more hospital pharmacists with advanced training and experience in clinical practice, we support the enhancement and expansion of these programs.

**8.41** The Committee therefore recommends that by 1991 the Ministry of Health, or other appropriate granting agency, provide the necessary funding to increase both the stipend paid to hospital pharmacy residents and the number of positions available for such residents.

### **8.3.4 Investigational Drug Use for Clinical Trials**

It has been drawn to the attention of the Inquiry that hospitals which do not have established procedures for the initiation of a clinical drug trial may be absorbing costs not directly associated with patient care. Furthermore, if the pharmacy and therapeutics committee of the hospital does not have procedures to evaluate and authorize acceptance of the protocols for clinical drug trials prior to administration, the hospital does not have control of drug use in the patient population.

**8.42** The Committee therefore recommends that by 1991 the Ontario Hospital Association, the Ontario Medical Association, the Ministry of Health and the Ontario branch of the Canadian Society of Hospital Pharmacists review the mechanisms for control of investigational drug use for clinical trials in hospitals with a view toward the establishment of standards and ethically appropriate methods of cost containment.

## **8.4 Role of Home Care and Other Health Care Workers**

The focus of the role of home care workers, occupational therapists and other health care workers in the community is maintaining the person in the home. An important aspect is in the area of compliance monitoring of patients. The need for these services generally arises after the diagnosis has been made, and the

prescription written by the physician, and after the prescription has been filled by the pharmacist and delivered to the patient.

Some individuals, functioning well in other areas, need the drug therapy to be administered in order to ensure compliance. This may be because of handicaps, or just because administration is physically difficult. For example some products, such as insulin, must be administered by injection.

### **8.4.1 Needs of Caregivers**

If the patient requires compliance monitoring beyond that which is normally given by the physician or pharmacist at the time of delivery of the prescription, the individual who performs the monitoring as part of the caregiving function must have several things: the legal ability to perform the function (with respect to liability for errors made in carrying out familial or professional duties); the degree of education required to administer and monitor medication; and the ability to physically perform the task, using mechanical or other aids.

Persons who monitor the administration and compliance of medication regimens are often not professional health care workers. Very often this type of function is performed by family members, and it is only when the family member becomes unable or unwilling to perform this function that a professional health care worker is called in. In some situations, this role may be performed by close friends.

Legal liability for the administration of medications by a family member is less of a concern. But in the case of professional or paid health care workers, potential liability may be a major obstacle to the fulfilment of a needed function. The individual or group called upon to perform a function which may carry serious consequences for errors will

understandably be reluctant to perform such functions. Therefore, the individual or group must have protection, either in the form of legislative limitation of liability or affordable insurance.

**8.43 The Committee therefore recommends that a statutory limitation of liability for administration of medications should be established, in order to relieve associations, and individuals working for such associations under delineated conditions, from liability for administering or monitoring medication in residential settings.**

In addition, the functions to be performed must be well understood by the persons who administer medications and who must also possess the required communication skills to monitor compliance.

**8.44 The Committee therefore recommends that courses in the skills required by health care workers to administer medication and monitor patient compliance in residential settings should be developed and made available through public health care programs.**

#### 8.4.2 Services Available

In Ontario, many home support services—both government funded and private—are already in place. Furthermore there are out-patient services attached to institutions; there are community centres; and there are volunteer groups with interests in specific disease entities. Although none of these have been structured to deal specifically with medications, it is possible they can be utilized to oversee and/or encourage drug compliance.

Home care, a government funded support system created to maintain persons in the community, utilizes paramedical personnel and homemakers in its programs. The nurse

on the program is designated to teach medication regimens. She/he may fill medication devices and counsel the patient and/or family in the proper use of the drugs.

It is expected that in general the patient or a family member will be taught the medication regimen. However, many people in community programs suffer from varying degrees of forgetfulness and may have no family members nearby. If it is felt that the individual is non-compliant, the services of home care can be withdrawn on the premise that it would sustain a hazardous home situation.

Rather than force institutionalization by withdrawing services, it might be fruitful to consider developing surrogate family members. Homemakers attached to the home care program could be taught how to help a person remember to take medications. There is no suggestion here of administering the drugs; it would be merely to remind the person of the need to take the medication.

In subsidized housing, such as seniors' apartments or Ontario housing, there must be many people who would be willing and able to act as 'reminders' to a forgetful neighbour, especially if a stipend were attached to the service. There would have to be a person designated to be available for consultation, much of which could be done by telephone. This individual could be attached to the home care program, the public health department, a community medical clinic, or any other setting which staffs professionals with a medical background. A surrogate family member would not only be able to help the patient with his or her drug regimen, but would also recognize and respond to an adverse drug reaction. For the neighbours, such a program could provide the means of augmenting income, while providing the opportunity of a positive interaction with another person. Funders of the health care system could realize a reduction of costs for



professional visits and a possible reduction in the rate of institutionalization, be it acute hospitalization or long term care.

Community Occupational Therapy Association (COTA), funded by government, is another viable resource. The forte of the occupational therapists is their knowledge and creativity in devising ways and means to maintain a person functioning independently. This knowledge base is available to organize medical routines. Over and above knowing the usual compliance aids on the market, they can evaluate the ability of the person to use the device and, should this be a problem, either adapt it or create another method, such as using egg cartons, for organizing drugs. The occupational therapists depend not only on teaching methods but also upon establishing a relationship with their patients and patients' families to gain cooperation. They may visit the home as often and as long as they feel their services are beneficial.

COTA has also trained, and supervises, a corps of 400 volunteers who can be utilized to reinforce developed programs, freeing the occupational therapist to visit new patients.

**8.45 The Committee therefore recommends that programs which provide for drug therapy compliance monitoring and drug administration and reminders should be encouraged and funded in community and public health programs.**

Community assessment teams, day hospitals and day care centres are being developed in an attempt to prevent hospitalization and institutionalization and as a possible means to shorten hospital stays. Assessment teams have a physician attached to them and a pharmacist is usually available for consultation. It is assumed that drug reviews form part of the total assessment. What is often lacking is follow up of recommendations. Their influence could be enhanced if, in the area of

drug review, the teams could be encouraged to develop means of helping compliance with the recommended drug program, or enlist the cooperation of community organizations.

By definition, medical and paramedical staff are attached to day hospitals and patients are expected to attend from one to several days a week. In this setting there should be no difficulty in assessing drug needs, teaching the individual and/or family the regimen, teaching the rationale for compliance, and noting the capability of individuals to carry through the program. Again, ingenuity may be needed to simplify drug groupings and organize a system to recall times of ingestion, whether this is done by mechanical means or by arranging for family members or community volunteers who remind the patient when medication is due.

Day centres are often structured specifically for the cognitively, emotionally or physically impaired and these programs depend upon stimulation and social supports. However, while attending the centre, staff can remind participants when it is time to take medication. It is assumed that staff will report any concerns regarding patients to relatives or family physicians. It is hoped that when there is a need to encourage participation by a community service, such as public health, the day centre will initiate the process.

Centres should also be developing educational programs for their patients and caregivers, which can include inviting medical and paramedical personnel to speak on specific topics pertinent to the clientele. Day centres also have the ability to develop volunteer groups with special interests and knowledge which can become a source of support outside the centres.

**8.46 The Committee therefore recommends that drug therapy compliance monitoring programs be included as part of the approved programs developed or implemented by community assessment teams, day hospitals and day care centres.**

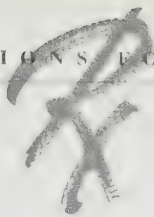
Senior centres, catering to the well-elderly, have developed vibrant programs which include education on maintaining healthy lifestyles. Their focus is on prevention. They have the ability to organize lecture series, health fairs, “brown bag” programs for drug reviews and other activities which are open to members of their communities. They are also capable of organizing volunteer programs which can reach out to the housebound. They represent a latent fount of expertise and ability which has yet to be tapped.

Individuals who can afford it have no difficulty in buying help with their care, which can range from having medications brought to them to assistance in administering drugs. There are numerous private health care agencies with personnel ranging from homemakers to registered nurses who are available on an hourly or sessional rate.

For the vast majority, who cannot afford such a service, there is some assistance available through community agencies. More can be developed utilizing professional personnel, working with volunteers, to provide individuals with the level of help they may require. Cost savings will be from more efficient use of professional services, more effective use of drugs, a decrease in iatrogenic diseases, and a decrease in hospitalizations and use of long-term care institutionalizations.







## Chapter IX

### Utilization

*This chapter looks at the demographics of health care consumers in Ontario and recommends drug benefit coverage for certain categories of individuals not now covered and co-payments for others. The chapter also deals with drug utilization review, adverse drug reporting, misuse and abuse of prescription medications, public education concerning drug abuse and limitations on the prescribing of sedatives, hypnotics and tranquilizers.*

#### 9.1 Role of the Consumer

##### 9.1.1 Introduction—a Demographic Profile

In 1989, an estimated 9.5 million residents of Ontario were consumers of health services, including pharmaceutical care.

Since the last census was conducted in 1986, data from that year are used to provide a demographic profile of the 9.1 million Ontarians counted. Slightly more than half (50.9 per cent) of the people were females. About one-fifth (20.5 per cent) were under the age of 14; 68.6 per cent were between the ages of 20 and 64 years; 10.9 per cent were 65 years of age or older. The age and sex population for Ontario has a bulge in it representing the 2.3 million residents who were born between 1950 and 1965. The bulge, 25.3 per cent of the populations, indicates the impact of the post-war baby boom.

Attention has been given to the increasing numbers of persons 65 years of age and older and their uses of health and social services. If current population trends continue, the number of persons reaching old age will continue to increase until about the year 2030, when

the last of those born during the post-war baby boom reach the age of 65.

Persons completing the census forms in 1986 were asked where they lived in 1981, the year of the preceding census. The results apply to the 8.4 million residents five years of age and older. The majority—4.6 million individuals—maintained the same residence over the five year interval; 2.0 million residents had moved within the same municipality; 1.2 million moved within Ontario; 286,000 came from other provinces; and 221,300 immigrated from outside Canada. Over this time, 186,170 people five years of age and older left Ontario to live in other provinces. The number of people who left Ontario to live abroad is unknown.

With respect to ethnicity, most Ontarians—61 per cent—were of British descent. The other major ethnic groups identified were French (531,580), Italian (461,375), German (285,155), Dutch (171,150), Chinese (156,170), Portuguese (139,220), and Jewish (127,030). Indians, Metis, and Inuit totalled 167,375.

Of these, 86.1 per cent spoke English only; fewer than one per cent (0.6 per cent) spoke French only; and 11.7 per cent were bilingual. About 143,000 residents spoke neither English nor French.

Three-fourths of Ontarians lived in private households headed by husbands and wives; 8.3 per cent lived in single parent families. The remainder lived in non-family households.

The majority of the residents in the province live in metropolitan areas with populations of 100,000 or more. Metropolitan Toronto had 3.4 million residents in 1986; there were 2.8 million inhabitants in the other metropolitan areas in southern Ontario, and 270,000 lived in Sudbury and Thunder Bay, the largest cities in northern Ontario.

The people of Ontario come from diverse places and ancestries and the mosaic varies from region to region and community to community. The goal of government continues to be to provide access to health care without respect to age, sex, income, ethnicity, or region of residence. One could add that access is to be guaranteed without respect to the type of health problem.

**9.1.1.1. A Health Profile of Ontario:** "Health Profiles of the Citizens of Ontario: Health Objectives, Performance Indicators, and Surveillance Techniques"<sup>1</sup> was written by Larry Chambers for the Ontario Health Review Panel in 1987; his report continues to be current. The report deals with the burden of ill health and the uses of prescribed and non-prescribed drugs to control health problems. It begins with the patterns of mortality, health problems in the community, uses of health services and a profile of the burden of ill health.

**9.1.1.2 Patterns of Mortality:** Cardiovascular diseases account for 46 per cent of all deaths; cancer is the second leading cause of death at 28 per cent; accidental deaths, at 8 per cent, are third. Over the past 20 years the age-

standardized mortality rates for cardiovascular diseases, accidental deaths, and other leading causes of death, with the exception of cancer, have been on the decline. While there has been notable success in combating some cancers, particularly those that are treated in the early stages, death rates for malignant diseases continue to increase.

To estimate the burden of ill health resulting in death, the focus can be shifted to the age at which individuals die. The concept of potential years of life lost (PYLL) is based on the idea that a death before a given age—usually 75 years—is viewed as an early death. If a person dies of a heart attack at age 45, the death would represent 30 PYLL. A 20 year old killed in a traffic accident would represent 55 PYLL. The method implies that deaths occurring at an early age impose a greater burden or loss on society than deaths that occur at an advanced age.

PYLL's are expressed in thousands of life years lost. The five leading causes of PYLL for Canada in 1986 were cancer (429,000 years), cardiovascular disease (290,000 years), motor vehicle accidents (160,000 years), all other accidents (124,000 years), and suicide (127,000 years). Congenital anomalies and perinatal mortality each contribute about 90,000 PYLL. The PYLL rates are higher for males than females for all leading causes of death.

Life expectancy can be defined as the average number of years of life remaining for persons at a given age. The average life expectancies at birth in 1985 for males and females born in Canada were approximately 72 and 80 years respectively. While the average life expectancy has increased for both sexes over the past 20 years, the rate of increase has been slightly greater for females than males.

<sup>1</sup> Chambers, Larry W., *Health Profiles of the Citizens of Ontario: Health Objectives, Performance Indicators, and Surveillance Techniques*, Canadian Public Health Association, 1987.

Obviously the differences in life expectancy are related to the differences in PYLL noted above.

### 9.1.2 Health Problems in the Community

Health surveys are used to estimate the prevalence of health problems in the community and the impact the problems have on the lives of individuals. The last major survey conducted in Ontario was during the pilot testing of the Canada Health Survey in 1978-1979.

The Canada Health Survey was not implemented as an ongoing survey as originally planned. Statistics Canada periodically conducts general surveys, and some of these are focused on health-related issues. There have been surveys on health and support in 1985, and work and disability in 1986, and results are reported by province. The government of Ontario is planning to conduct periodic health surveys, and the first one will be inaugurated this year.

Health survey results are based on self-reporting of health problems, limitations and disabilities and the uses of health services and drugs; consequently there may be errors and biases in self-reporting. Furthermore, persons in institutional care, and those too sick or old to respond, are excluded and the results apply to individuals living in the community who were able and willing to complete the interview.

Three trends in the prevalence of health problems by age and sex are noteworthy: individuals under 65 years of age tend to have acute health problems that are time limited in their effects; older persons tend to have chronic problems that require long term attention, and the problems are more likely to limit activities or mobility; and women are more likely to have chronic and disabling conditions than are men.

Arthritis and rheumatism, hypertension, limb and joint disorders, heart disease, and hearing and sight disorders were the most common complaints of persons 65 years of age and older, according to the Canada Health Survey.

The burden of health problems was measured within the framework of the concept of "annual disability days" which combine bed days, days with a loss of major activities, and days with cut-down activities. Adjustments were made to eliminate double counting and to make the annual estimates. There were 15.5 annual disability days for Ontarians in 1978-79. The rates by age were as follows: under 15 years—8.3 days; 15 to 64 years—15.9 days; and 65 years and older—31.5 days.

There are two other trends found consistently in health surveys. First, the prevalence rates for health problems and disability are higher for women than for men. Second, there are important differences in health status related to indicators such as education and income. Individuals with lower levels of income and lower levels of education are at a distinct disadvantage with respect to health status; they do not enjoy the same level of health as those with higher social and economic status.

The findings on health and disability were essentially confirmed in the 1985 general social survey.

In spite of the increasing burden of ill health, the mood and spirits of Canadians remain high. When survey respondents were asked to rate their status, 82 per cent rated their health as good or excellent. Persons who were 75 years of age and older were more likely to report lower ratings; even so, 57 per cent rated their health as good or excellent; 32 per cent rated it fair; and only 12 per cent said they were in poor health. Canadians in general report high levels of happiness. Fewer than 10 per cent, regardless of age, reported they were unhappy.



Satisfaction with health did decline with age and the use of medical services. About one-fifth of the aged reported they were dissatisfied with their health, as compared to 10 per cent of the young adults. In the U.S., Herzog and Rodgers (1983) noted that satisfaction with life increases with age, even though satisfaction with health declines. When it comes to health, only in the face of severe disabling conditions or mental illness does life satisfaction and happiness markedly decline.

### 9.1.3 The Uses of Health Services

Generally speaking, the latest data available on the costs and uses of health services are for 1985, and while absolute uses and costs of health services have increased since, the profile remains basically the same. According to Health and Welfare Canada, the total expenditures for health care in Ontario in 1985 were \$14.5 billion dollars—approximately \$1,600 for every individual in the province. The breakdown of the distribution of expenditures is presented in table 9.1. Half of the expenditures were for institutional services; about one quarter were for professional services; 13.5 per cent were for drugs and appliances; and the remaining 10 per cent were for other health expenses.

**9.1.3.1 Institutional Care:** Three-fourths of the costs for institutional services were directed toward hospital care. During fiscal 1987/88, there were 1.4 million admissions into hospitals in Ontario. One can estimate that 85 per cent of the admissions were first admissions, while the remaining 15 per cent were for persons admitted two or more times during that year. There were 52,089 approved beds in Ontario in that year, or 5.6 beds per 1,000 population.

**Table 9.1**

#### **Total Health Expenditures in Ontario, 1985 by Category in Millions of Dollars**

<b>Total Expense</b>	<b>14,538.5</b>
<b>Personal Health Care</b>	<b>13,034.5</b>
<b>Institutional and related services</b>	<b>7,292.8</b>
Hospitals	5,509.9
Other institutions	1,509.4
Home care	136.6
Ambulances	136.9
<b>Professional services</b>	<b>3,779.9</b>
Physicians	2,617.0
Dentists	928.5
Other professionals	234.5
<b>Drugs and appliances</b>	<b>1,961.8</b>
Prescribed drugs	932.6
Non-prescribed drugs	710.8
Eyeglasses	256.7
Hearing aids	23.8
Other appliances and prostheses	37.9
<b>Other health expenses</b>	<b>1,504.0</b>
Prepayment administration	205.8
Public health	425.7
Capital expenditure	569.7
Health research	127.0
Miscellaneous health costs	175.7

Source: *National Health Expenditures in Canada 1975-1985*, Health and Welfare Canada, Nov. 1987.

There were 4.1 acute care beds per 1,000 population; they accounted for 96.9 per cent of all hospital patients and 71.0 per cent of hospital days. The average length of stay for acute care patients was 8.7 days at the average cost of \$344.34 per day.

The most common diagnoses for acute care hospital days were related to circulatory diseases (17.6 per cent), cancer (10.4 per cent), mental disorders (9.6 per cent), digestive disorders (9.0 per cent), injuries and poisonings (7.8 per cent), pregnancy and

childbirth (7.0 per cent) and respiratory diseases (6.8 per cent). The surgical procedures most frequently performed were obstetrical procedures (21.3 per cent), cardiovascular operations (7.5 per cent), tonsillectomy and/or adenoidectomy (4.3 per cent), hernia repairs (4.0 per cent) and hysterectomies (3.2 per cent.) Other surgeries commonly performed include appendectomies, cholecystectomies, transurethral prostatectomies and dilation and curettage.

Chronic beds accounted for fewer than 5 per cent of hospital patients, but chronic patients had 25.2 per cent of all hospital days. The average length of stay per admission was 267.4 days at a cost of \$169.18 per day.

Residents of Ontario received care in other institutional settings as well. The types of facilities (number of beds) include those for aged persons (49,200 beds), the mentally handicapped (16,918), the physically handicapped (6,427), emotionally disturbed children (3,263), the retarded (811) and substance abusers (789). There were 3,295 in beds in other facilities. About 90 per cent of the beds are occupied at any one time, but information on the number of admissions, the average length of stay, and the cost per day for the various facilities, was not available. Ontario, like the rest of Canada, continues to have a high rate of institutional care for health related problems.

**9.1.3.2 Professional Services:** The next major category of expenditures was for professional services, which accounted for 26 per cent of total expenditures; 70 per cent of expenditures on professional services were for physician fees; 5 per cent were for dentists; and the remaining 25 per cent were for other health professional services.

**9.1.3.3 Drugs and Appliances:** Expenditures on drugs totalled \$1.6 billion and \$300 million was spent on eyeglasses, hearing aids and other appliances. Data from IMS (a data

service specializing in medical information) indicate that drug companies sold \$1.089 billion in prescribed drugs to Ontario drug stores in 1988. The Ontario Drug Benefit (ODB) program paid \$354.9 million of the prescribed drug costs during that year, exclusive of dispensing costs and the 10 per cent surcharge on the costs of the drugs. Added to that are drug expenditures by hospitals, which totalled \$215.7 million. Public expenditures on prescribed drugs were approximately \$570 million, or about 44 per cent of the total.

The data on the total sales of non prescribed drugs in Ontario are not available for 1988, but Health and Welfare Canada estimated that about \$710.8 million was spent in 1985. The ODB spent about \$43 million for claims for non-prescribed products, or about 6 per cent of that amount.

**9.1.3.4 Other Health Expenses:** The remaining categories of health expenditures include capital expenditures (3.9 per cent), public health (2.9 per cent), administration of health services (1.4 per cent), research (0.9 per cent) and other costs (1.2 per cent).

**9.1.3.5 The Uses of Health Services and Drugs in the Community:** The principal reasons for using drugs are to maintain health and manage illness. Drugs may be used as a part of self-care initiative or on the advice of physicians or other professionals. Within a given year, 82 per cent of ambulatory Ontarians can be expected to visit a physician, averaging six visits a year. From the Canada Health Survey, one can estimate the percentages of individuals with one or more consultations with health professionals in a given year. The health professionals, and the percentages of individuals who contacted them are as follows: dentists (50 per cent), optometrist/optician (21 per cent), nurse (13 per cent), pharmacist (5 per cent), chiropractor (5 per cent) and psychologist, social worker or counsellor (3 per cent).

In the survey, one-third of the persons with health problems did not consult a physician. The decision to seek help depended on the nature of the problem. If problems were relatively serious (e.g. diabetes, thyroid disorders, hypertension, or heart disease) medical care was likely obtained. For minor acute problems such as respiratory infections or the flu, individuals reported that the problem was not serious enough to warrant a visit to the physician. Nor did individuals seek help if they thought the problem was under control. Individuals cited time or costs as factors for not seeking care for about 5 per cent of problems.

The most commonly used drugs were vitamins and pain relievers and most of these were taken without the advice of a physician. The most commonly used prescribed drugs were heart and blood pressure medicines, tranquilizers and antibiotics; most of these were taken on the advice of a physician.

Women were more likely to report the use of medications, particularly vitamins, pain relievers and tranquilizers; 22 per cent of the women between the ages of 15 and 44 reported taking birth control pills. Of women between the ages of 45 and 64, 14.6 per cent reported taking hormone pills.

Individuals 65 years of age and older reported the highest rate of drug usage. Nearly 40 per cent of older women and 30 per cent of older men were taking heart and blood pressure medicine. The next most commonly used drugs were vitamins, pain relievers and tranquilizers. The health problems most common among the elderly are related to cardiovascular disease; arthritis, rheumatism and problems with limbs and joints; and mental problems. These conditions impose limitations on activity and are the major causes of disability days. The use of drugs is

the key to maintaining the health status of the elderly in Ontario.

As suggested by the data from the Canada Health Survey, individuals engage in self-care and take drugs without consulting a physician. There are two additional decisions that individuals make that the survey did not address. It is generally estimated that about one-fifth of all prescriptions written by physicians are not taken to the pharmacist to be filled. Furthermore it is generally believed that the rate of true compliance is only about 50 per cent. This means that about half of the time, drugs are not taken as prescribed, at the wrong times, or in the wrong amounts. It is very difficult to estimate the impact that unfilled prescriptions and non-compliance have on the health and illnesses of individuals.

#### 9.1.4 The Burden of Ill Health

Wilkins and Adams (1983)<sup>2</sup> combined data on institutional care with the data from the Canada Health Survey to provide a profile of the "healthfulness" of life. They defined six health states: activities not restricted, short term disability only, minor activity restriction, restriction of major activity, impossible to perform major activity, and long term institutional care. While the average life expectancy was about 72 years for males and 80 years for females, the average health expectancy—years free of limitations—was 60 years for males and 63 years for females. Although women live longer than men, they spend more time in disabled states and the differences in health expectancy are considerably less than difference of years of life expected.

By comparing the results of the 1978 health statistics and the Canada Health Survey with health statistics from 1951 and the Canada

<sup>2</sup> Wilkins, R. and D.B. Adams, "Health Expectancy in Canada, late 1970s: demographic, regional and social dimensions," *American Journal of Public Health*, 75(9): 1075-80 (1985).



Sickness Survey, Wilkins and Adams (1987)<sup>5</sup> estimated that while the life expectancy rose by 4.5 years for males and 7.5 years for females, the expected years free of limitations increased by 1.3 and 1.4 years respectively. This suggests that there was a trade off between death and disability: 70 per cent of the gain in life years for men and 80 per cent of the increased years for women were spent in states of disability.

Working from a scale where death is given a value of 0 and normal healthy life is valued as 1, they gave the various disability states values ranging between 0 and 1. The values were 0.4 for long term institutional care, 0.5 for unable to do major activity, 0.6 for restriction in major activity, 0.7 for minor restriction in activity, and 0.5 for short term disability. The person years expected for each disability state were multiplied by these values, to arrive at a figure for quality adjusted life expectancy, or life years. Between 1951 and 1978, the average life expectancy increased by 6.0 years for all Canadians, but the quality adjusted life expectancy increased by only 3.7 years. While the average gain of life expectancy was 6.0 years, 4.7 of these were spent in disabled states and 1.3 years were disability free. Quality adjusted life expectancy varies by region of the country, sex, and income. The quality adjusted life expectancy for Ontario is 69.1 years. By region, the lowest value was for the Atlantic provinces (67.8 years) while the Prairies had the highest (69.2 years). As one would expect, the quality adjusted life expectancy is higher for Ontario women (72.1 years) than for Ontario men (66.1 years).

Wilkins and Adams categorized the income of Canadians into quintiles. Canadians in the top quintile had an average life expectancy of 76.4 years. Persons in the lowest quintile for income had an average life expectancy of 71.9

years and a quality adjusted life expectancy of 64.6 years. For every indicator of morbidity, disability, and death, low income is associated with poor health outcomes.

There is considerable debate by demographers and epidemiologists as to whether the prevalence rates of disability have increased over the past 20 years. Rates of long term institutional care of the elderly have increased in Canada. In the early 1960s, the rate of long term institutional care was 6.4 per cent for elderly Canadians and by 1984 this had increased to 7.8 per cent. Similar increases have been observed in the U.S.

There is controversy about levels of self-reported disability because of the changes in methods and the ways in which questions were worded. There is agreement that the self-reported disability has increased for all age groups, although some would argue that the changes are artifacts of variations in methods.

Verbrugge<sup>4</sup> who believes the changes are real, has studied the changes in morbidity and mortality for middle-aged and older persons in the U.S. She has noted the patterns of morbidity and mortality for "killer" and "nonkiller" conditions. With respect to killer conditions, there is the pattern of rising morbidity and declining mortality (e.g. diabetes, heart diseases, hypertension, and cerebrovascular diseases), rising morbidity and mortality (e.g. malignant neoplasms, asthma, chronic obstructive lung diseases in the elderly), declining morbidity and mortality (e.g. hernias and nephritis in elderly men), and declining morbidity but rising mortality (e.g. cirrhosis of the liver in elderly men.) With respect to non-killer diseases, she has noted the patterns of rising morbidity (e.g. respiratory, musculoskeletal, and some skin

<sup>5</sup> Wilkins, R. and D.B. Adams, "Changes in the healthfulness of life of the elderly population: an empirical approach," *Review Epidemiologique Santé Publique* 35(3-4): 225-35.

<sup>4</sup> Verbrugge, Lois M. "Longer Life but Worsening Health? Trends in Health and Mortality of Middle-aged and Older Persons," *Milbank Memorial Fund Quarterly Health and Society*: 1984; 62(3): 457-519.

conditions) and declining morbidity (e.g. varicose veins, haemorrhoids, peptic ulcers, and gallbladder diseases.) In summary, the general trends show a rise in chronic and disabling conditions, with declining morbidity observed for only a few indicators.

Canada, as well as the U.S., is in an era of longer life and declining health. Worsening health in the community can most likely be attributed to the higher incidence of chronic diseases, earlier diagnosis of chronic conditions, earlier accommodations in activities for disease, and improved survival. Longer life is most likely due to earlier or better treatment of chronic conditions, improved self-care for disease, and improvements in medical care technology (e.g. neonatal intensive care, trauma care, medical and surgical management of heart conditions, transplants, and so on.) As Verbrugge notes, increased morbidity and declining mortality can be seen as logical result of the medical and social changes that have occurred in the last 25 years.

### 9.1.5 Ontario Drug Benefit Program—Use and Access

**9.1.5.1 The Growth and Use of the Ontario Drug Benefit Plan:** The ODB plan was originally designed to provide drug coverage for persons 65 years of older. The government extended the benefits to cover other groups of residents, including recipients of family benefits and general welfare assistance who require assistance with large drug bills, and patients in home care and extended care programs.

In the fiscal year 1976/77, the ODB plan had 861,476 beneficiaries who made claims which cost government \$67.7 million. During the last fiscal year, 1988/89, 1.5 million beneficiaries made 35.4 million claims at a cost of \$638.1 million. If the costs are stated in 1988 dollars adjusted for increases in the consumer price index (CPI), the cost of the program increased

from \$154.2 million in 1976/77 to \$630 million, an increase of 313.8 per cent.

There are six basic components to ODB costs: 1) the number of ODB claimants; 2) the average number of claims per claimant for which there is a dispensing fee (prescribed drugs); 3) the average dispensing fee per claim for prescribed drugs; 4) the average cost of the prescribed drugs per claim; 5) the average number of claims for non-prescribed drugs per claimant; and 6) the average cost per claim for non-prescribed drugs.

The component costs of the ODB program have increased at different rates. To determine the rates of increase for the various components, increases over the 12 years were indexed to the 1976/77 fiscal year and all dollar amounts are stated in constant 1988 dollars.

If all components had increased at the same rate as the CPI, there would have been no increases in the costs of the ODB program as expressed in constant 1988 dollars. The levels of activity and costs of each component were adjusted to the 1988/89 value; values for the other components were held at the 1976/77 levels to determine the increase in constant dollars that can be attributed to that component.

For example, the number of claimants increased from 861,476 individuals in 1976/77 to 1,501,409 in 1988/89. If one allows for the increase in the number of claimants, while assuming that the number and cost of claims for prescribed and non-prescribed drugs remained at the 1976/77 levels, one could determine the rate of increase in the costs of the ODB program due to the increased number of claimants per se.

The components were adjusted one at a time to determine the impact of each on ODB costs. Over the 12 year period, the component with the highest rate of increase was the number

of claimants. The increased number of claimants alone would have resulted in a 74.3 increase in costs. This component is determined by the ageing of the population and by government changes in eligibility for coverage.

The component with the second highest rate of change was the average number of claims for prescribed drugs per claimant. Assuming that the general levels of health of the claimants had not changed over the period, the increase could be attributed to the prescribing patterns of Ontario physicians. To the extent that the case mix of claimants changed, an increase in the average number of claims per claimants could reflect the changes in the health levels of the claimants. If only the average number of claims for prescribed drugs had changed, there would have been a 50.1 per cent increase in the costs of the ODB program during the 12 year period.

The average cost of prescribed drugs was the third most important component driving costs. If all other components had remained the same and only the price of drugs had changed, the increase in the constant dollar costs would have been 48.4 per cent over the 12 years. The increase in drug costs could be due to the introduction of new, improved, and more expensive drug products, changes in selection of drug products by the physicians, and the inclusion of the 10 per cent upcharge in the price of the prescribed drugs.

The costs associated with the average dispensing fee, the average number of claims for non-prescribed drugs, and the average costs per claim for non-prescribed drugs, remained at levels consistent with changes in the CPI. The increases associated with these components were 3.2 per cent for dispensing fees, 4.0 per cent for average number of claims for non-prescribed drugs, and 1.6 per cent for the average cost of non-prescribed drugs per claim. Clearly, these costs did not contribute in any important way to the overall increase in the costs of the ODB program.

**9.1.5.2 Relative Importance of Components to Overall Increases in Program Costs:** The total costs of the ODB increased by some \$476 million over the 12 year period. We can take the \$476 million increase as the base amount and assess the relative importance of the components in accounting for this increase. The increase in the number of claimants accounts for \$114.6 million of the increase. Increases attributable to the average number of prescriptions and average cost of prescribed drugs are \$77.3 million and \$74.7 million. Increases attributable to dispensing fees, claims and costs of non-prescribed drugs are minimal.

Stated another way, 24.2 per cent of the increase is due to the increased number of claimants; 16.2 per cent is due to the average number of prescriptions; and 15.7 per cent is due to the average costs of prescribed drugs. Individually, these components account for 56.1 per cent of the \$476 million increase in costs. There were more claimants, each claimant had more prescriptions, and the costs per prescribed drug increased. The effects of the three components become multiplied, and the multiplicative effects accounted for 39.3 per cent of the costs above and beyond the increases due to the independent effects of the three major components.

Less than 4 per cent of the \$476 million increase could be attributed to the independent and multiplicative effects of the dispensing fee, and the claims for, and costs of, non-prescribed drugs.

**9.1.5.3 Use of ODB by Type of Beneficiary:** The ODB plan covers persons 65 of years of age and older (995,800), persons receiving family benefits (233,400) and general welfare assistance (237,900) who require assistance with drug bills, and patients in home care (21,300) and extended care programs (9,900). Even though the eligibility criteria for persons receiving family benefits or welfare have broadened, the largest increase in the number of claimants was due to the ageing of the



population. The number of claimants increased by 640,000, and the increase in the number of elderly accounted for 63.8 per cent of the increase. In 1976/77, 68.3 per cent of the claimants were 65 years of age or older; in 1988/89 they made up 63.4 per cent of those receiving Ontario drug benefits.

The average annual cost of claims for the aged was about \$512; it was \$486 for those on extended care and \$322 for persons on home care. Average cost for Ontarians receiving family benefits and general welfare assistance was \$377 and \$137 respectively. Even with the expansion of the ODB for recipients of home care, family benefits, and general welfare assistance, 80 per cent of the programs were for the aged, and this percentage was essentially the same as for the 1976/77 fiscal year.

**9.1.5.4 The Projected Growth in the Numbers of Elderly:** Between the 1976 and 1986 censuses, the number of Ontarians over 64 years of age increased by 34.5 per cent, from 739,000 to 994,000. The Ontario Treasury Board set forth assumptions about future trends in fertility, mortality and migration to estimate the growth of the population of Ontario through the year 2011. Their estimates indicate that there will 1.9 million Ontarians 65 years of age and older by 2011, or 86.2 per cent more than there were in 1986.

The aged are frequently grouped into three categories: the young-old (65 to 74 years), the middle-old (75 to 84) and the old-old (85 and older.) In 1976, 8.2 per cent of the aged were the old-old, who should make up 13.5 per cent of the aged in 2011. Stated another way, the age composition of the elderly should shift toward the later years.

The figures are deceptive. Generally, health care costs increase with age, rising dramatically within the year preceding death. As the probability of death increases with age, the data per se suggest that age, in and of itself, is an important determinant of cost. In

fact, health care costs of the aged who live independently in the community do not increase dramatically with age and this is specifically true for the costs of drug benefits.

## **9.1.6 Access to Other Drug Plans in Ontario**

ODB claimants comprise about 16 per cent of Ontarians; they account for about 45 per cent all prescribed drugs. We asked Prof. Jeremiah Hurley to undertake a study of access to drug insurance for residents not covered by ODB and the material in this section comes largely from his report. (See volume II.)

### **9.1.6.1 Coverage by Private Insurance:**

Virtually all private health insurance plans that cover the costs of prescribed drugs are provided through group plans at the place of employment. With rare exceptions, private drug plans do not cover non-prescribed, or over-the-counter drugs.

The two largest insurers are Blue Cross and Green Shield. In 1988 Blue Cross provided coverage to 1,029,975 individuals, comprised of subscribers and their dependents. Green Shield provided coverage for 460,177 individuals in 1987, so one can estimate that the two plans cover about 1.5 million Ontarians. While Blue Cross and Green Shield are the largest private health insurers, 137 other insurance companies provided health benefits in Ontario in 1987. Together, they paid an estimated \$356 million in benefits in that year.

Most drug benefits are covered in plans that include other health benefits such as expanded hospital coverage, dental care, eyeglasses and health costs while travelling. As individuals may subscribe to more than one plan, the number of individuals covered under the plans can exceed the number of individuals in the province. The plans also vary with respect to co-payments and

deductibles, so it is nearly impossible to determine the degree to which drug costs of Ontarians are covered by private insurance companies.

Hurley contacted 36 of the larger trade unions and trade and professional organizations in an attempt to identify the degree to which drug plans are included as a fringe benefit of employment. However, most of them do not collect information on health insurance benefits offered through the place of employment.

He was able to draw a number of interesting conclusions from the information that was available: 1) all municipal employees in Ontario have some type of drug coverage, but the comprehensiveness of the coverage varies by municipality; 2) all provincial and federal government employees have drug coverage. Members of the Canadian Union of Public Employees pay a 20 per cent co-insurance rate toward the cost of each prescription; 3) most union members have drug coverage, but the percentage covered could not be accurately estimated; 4) about one-quarter of the members of the Ontario Federation of Agriculture have coverage through a drug plan promoted by the federation; and 5) according to the 1988-89 survey of wages and working conditions for hourly-paid employees, conducted by the Canadian Manufacturers Association, 96 per cent of the hourly employees in manufacturing industries have drug coverage. It should be noted that only 25 per cent of those contacted responded, so the findings are of limited value.

While it was not possible for Hurley to provide precise estimates, he found no evidence to refute the often quoted figure that 85 per cent of the residents of the province have some form of third party coverage. This would suggest that beyond the 1.5 million ODB

claimants, about 6.7 million Ontarians have private coverage, and 1.4 million residents are without third party drug coverage.

**9.1.6.2 Identifying Problems in Coverage:** It is incorrect to assume that persons with third party coverage are without problems in paying drug costs. Co-insurance, deductibles, and co-payments may serve as barriers to obtaining prescribed drugs. Some non-prescription drugs and nutritional supplements are not covered and there may be instances in which their costs are high for individual consumers. Furthermore drug plans may not cover conditions existing at the time the person enrolls, or may limit the amounts the plan will cover over the lifetime of the individual. Even so, there is a consensus that private insurance plans ensure basic access to prescribed drugs.

Lack of access to a third party drug plan may compromise the quality of health care received by two specific groups. The first consists of individuals in families, or unattached individuals, without insurance through the workplace, who have low incomes but are above the eligibility limits for family benefits or general welfare assistance. The second group is composed of individuals with extraordinary drug costs, particularly those with chronic diseases or disabling conditions who are not covered by disease-specific plans provided by the government, workmen's compensation, family benefits, general welfare assistance or the ODB. There is some overlap between the two groups as persons with chronic and disabling conditions may also be members of the low income group.

There is no definitive official definition of poverty in Canada. Statistics Canada, the Canadian Council on Social Development, the Metropolitan Toronto Social Planning Council, and the Senate's special committee on poverty

have provided guidelines for defining poverty. (Ross and Shillington 1989)<sup>5</sup>. Statistics Canada has defined low income cut-offs based on the proportion of average family income devoted to the essentials of food, shelter and clothing. The figures are adjusted for size of area of residence and the number of persons in the family. According to the guidelines, 9.3 per cent of families and 32.7 per cent of unattached individuals in Ontario had low incomes in 1987.

Using data from Statistics Canada, Hurley estimated that in 1987, 18 per cent of Ontario households—families and unattached individuals—had annual incomes below \$15,000. After subtracting the households receiving family benefits and general welfare assistance, and households headed by individuals aged 65 and over whose incomes were less than \$15,000, he estimated that there are about 138,000 low income households ineligible for public assistance or coverage for drug costs. At an estimated 3.5 individuals per household, this means there are 500,000 low income Ontarians in need of a drug plan.

Individuals with high drug costs could qualify for assistance through either of two municipal programs: special assistance or supplementary assistance. In the 1987/88 fiscal year, \$2 million were expended for drugs through these special programs. Hurley estimated that at most, this sum would have translated into benefits for no more than a few thousand households.

The second group consists of the chronically ill and disabled. During the 1986 census, questions were asked about disabled household members. Statistics Canada<sup>6</sup> conducted the follow-up health and activity limitation survey to collect extensive information on

disabled individuals. The results suggest that there were 674,330 disabled individuals between the ages of 15 and 64 years in Ontario in 1986-87. Their disabilities were classified as mild (54.2 per cent), moderate (30.0 per cent), or severe (15.8 per cent). It can be noted that 32 per cent of the recipients of family benefits and general welfare assistance are disabled. Working from the census data, about 55 per cent of disabled persons between the ages of 15 and 64 years had incomes below \$10,000; another 11 per cent had incomes between \$10,000 and \$14,999; 14 per cent had incomes between \$15,000 and \$24,999; and 18 per cent had incomes over \$25,000. The lowest income individuals are likely covered by social assistance programs. Those with incomes between social assistance eligibility and \$15,000 belong to the low income group.

About one-third of disabled adults under 65 years of age have incomes in excess of the \$15,000. There are no data on the drug expenditures of the 200,000 or so individuals who would fall within this group. About 190,000 disabled individuals had expenditures for prescription and non-prescription drugs, and 71,375 reported they did not have a plan for health and medical services. By definition, they would be under 65 years of age and not covered by social assistance.

There are an estimated 500,000 low income individuals not covered by old age and social assistance benefits. We can further estimate that there are between 60,000 and 190,000 individuals with disabilities who have incomes above the low income guidelines but should be considered for coverage under the ODB plan (table 9.2.) There are two estimates for the costs of extending ODB: the average cost for a general welfare assistance recipient of \$107 per year, or the average cost of \$337 per year for a recipient of family benefits.

<sup>5</sup> Ross, David P. and F. Shillington, *Canadian Fact Book on Poverty*, Canadian Council on Social Development, Ottawa, 1989.

<sup>6</sup> Statistics Canada, *Report of the Canadian Health and Disability Survey 1983-84*, cat. no. 82-555E, 1986.



The estimated annual costs for extending the coverage range from extremes of \$59.2 million to \$232.5 million. A mid-range estimated is \$150 million.

**Table 9.2**

**Costs estimates for adding low income and disabled persons to ODB**

	Cost estimates in millions	
	Low	High
Potential recipients		
560,000	\$59.2	\$188.7
690,000	\$73.8	\$232.5

In an interim report, the Inquiry recommended that coverage be extended to persons with cystic fibrosis and thalassemia; that recommendation was acted upon by the Ministry. There were also recommendations to the Inquiry that individuals with other diseases be covered, or that coverage be extended to all individuals with diseases which are managed through the extensive use of drugs. For example, the Advocacy Resource Centre for the Handicapped<sup>7</sup> recommended that Ontario drug benefits be extended for individuals with chronic arthritis, kidney disease, cancer, diabetes, and multiple sclerosis. Since the numbers of Ontarians with these and other chronic conditions are not known, it is not possible to estimate the number of individuals with catastrophic drug costs.

**9.1.6.3 Strategies for Extending Coverage:**

The Social Assistance Review Committee<sup>8</sup> noted that the loss of drug benefits served as a disincentive for individuals with earnings slightly above the limit to leave public

assistance. It recommended buffers in the eligibility criteria of \$50 per month for unattached individuals and \$100 for families, and the recommendation was implemented on October 1, 1989 in the supports to employment program (STEPS).

The Ministry of Community and Social Services subsequently made a further revision in eligibility requirements for STEPS. An individual with high drug costs and low income can apply for special assistance. Drug costs are subtracted from the income and if the amount remaining is below that required for basic needs, the individual is eligible for drug benefits. The impact of this policy, which is still being implemented, has yet to be determined.

The Inquiry recognizes that STEPS has resolved the problem of catastrophic drug costs for low income persons. However, the Inquiry recognizes that the dignity of individuals who have to pass the social assistance test—which considers circumstances and assets in addition to income—may be compromised. A mainstream program available to all individuals, and based on a means test, could cover catastrophic drug costs in an unobtrusive manner. For example, the criteria for the income means test could be the same as for the guaranteed annual income supplements for senior citizens. These are \$827 a month for single persons and \$1,373 for couples, and the income levels could be adjusted for the number of dependent children, as is currently the case with the social assistance programs. Individuals would be eligible if their monthly income, minus drug costs, fell below the criteria of the means test.

<sup>7</sup> Brief #150-3300.

<sup>8</sup> Thomson, G., chairman, *Transitions*. Report of the Social Assistance Review Committee, Ministry of Community & Social Services, Toronto, 1988.

The following recommendation assumes that the impact of the STEP program, and any modifications to it, are carefully assessed through well-designed studies to ensure that the program is accomplishing its intended objectives.

**9.1 The Committee therefore recommends that low income individuals, or individuals with catastrophic drug costs, who do not have coverage through a private health insurance plan, have drug costs covered through a plan based on an income means test, adjusted for the number of dependents, in accordance with social assistance guidelines, and that copayments should be introduced for individuals and families with incomes above social assistance levels.**

**9.1.6.4 Drug Plan Coverage and Cost-sharing:** Of the 9.5 million Ontario residents, approximately 1.5 million receive benefits under the ODB plan, and all their drugs costs are covered. The extension of the plan to include low income individuals, and individuals with catastrophic drug costs, could add an additional 690,000 recipients.

There are another 5.6 million Ontarians with drug coverage through private health insurance plans. Hurley was unable to obtain detailed information of the level of cost-sharing required by subscribers to the plans of 139 insurance companies providing coverage. But based on aggregate data provided by Blue Cross, the average cost per prescription was \$23.13 in 1988; the beneficiary paid \$1.59—or 7 per cent of this. The average subscriber paid \$18.91 in drug costs out-of-pocket for that year. The per prescription price to the subscriber of Green Shield ranges from zero to \$5; on average, subscribers paid 49.5 cents per prescription.

Even with the extension of the ODB plan to cover low income individuals and persons with catastrophic drug costs, there will still be between 700,000 and 800,000 individuals

without third party coverage for drug costs. One option for providing coverage for them is to extend OHIP to include drugs. A second option would be for the government to sponsor a plan, with or without cost-sharing, with private insurance companies for persons unable to secure coverage through the place of employment. Given the lack of apparent interest in either of these options, the Inquiry gave them minimal consideration.

Drug plan coverage of costs has a direct bearing on consumer behaviour. If drugs are free the consumer uses them more frequently than if he or she has to pay part or all of the cost. Physicians and pharmacists agree that the number of prescriptions written and dispensed increases when a patient becomes eligible for coverage under the ODB plan. In fact, physicians directly or indirectly ensure that patients receive the benefits for which they are eligible; pharmacists bill ODB directly for the drug costs and the patient is free to take advantage of the plan.

There is little question that the introduction of a fee or copayment for drugs reduces utilization. Hurley has reviewed the evidence on the impact of consumer responses to changes in costs of obtaining drugs. He first considered the impact of a charge of \$2.50 per prescription, and estimated that drug use would drop between 10 and 20 per cent. He further estimated the elasticity of demand for each additional \$0.50 increment in the charge per prescription. Elasticity of demand is defined as:

$$\text{Elasticity} = \frac{\text{Per cent change in use}}{\text{Per cent change in price}}$$

Hurley estimated the elasticity of demand to range between -0.10 (a 10 per cent decline in the use of drugs for every 100 per cent increase in the price of drugs) and -0.40. We are taking the value of -0.10 as an estimate of the minimum impact and -0.20 as an estimate of moderate impact.

The impact of introducing copayments is twofold. There is the initial reduction in drug use for a given copayment (between 10 and 20 per cent for a starting copayment of \$2.50) and the elasticity of demand for each additional \$.50 increment in the copayment (the most likely estimates range between -0.10 and -0.20). For consumers with a drug plan that covered all drug costs, a \$3.50 copayment would likely result in 13.6 per cent to 26.4 per cent reduction in use. Reductions in drug use for a \$5 copayment would be between 19.0 per cent and 36.0 per cent; it would be between 28.0 per cent and 52.0 per cent for a \$7.50 copayment.

Drugs taken vary in their appropriateness and effectiveness. Evidence from the experimental studies and the medicare services in the U.S. clearly indicates that the reduction in use related to copayment is unrelated to the appropriateness or effectiveness of the drugs. Consumers reduce their use of essential drugs as well as nonessential drugs but the impact of the reduction on their health is not known.

As noted, most residents of Ontario have drug coverage plans with cost-sharing in the form of copayments and deductibles. While all provinces have programs comparable to the ODB plan, four provinces/territories require no cost-sharing whatsoever. They are Ontario, Northwest Territories, Nova Scotia, and the Yukon. The other provinces require cost-sharing by beneficiaries not receiving social assistance, in the form of deductibles, coinsurance or a fixed charge per prescription, with or without a cap on expenditures. Saskatchewan and B.C. have recently introduced consumer charges, but the actual impact of the copayment on drug use by the aged and persons on social assistance has yet to be determined.

There are trade offs in ensuring access to drug coverage, consumer responsibilities for the cost of drugs, and government

expenditures on health care. Given the varying cost-sharing arrangements of private health insurance plans, the Inquiry considered the introduction of copayments in the form of fixed charges per prescription for seniors not receiving social assistance. About 60 per cent of seniors in Ontario have incomes beyond the eligibility criteria for guaranteed annual income supplements, which are \$827 a month for individuals and \$1,373 for couples. The Inquiry considered the impact of introducing \$3 or \$4 charge per prescription with a cap on expenditures of \$250 per year. That is, senior citizens not receiving GAINS would pay \$3 or \$4 per prescription, regardless of the cost of the drug, up to \$250 in any one year. After the cap is reached all drug costs would be covered. In the last fiscal year of the ODB program, the average cost per prescription was about \$18 so the recommended copayments would represent 17 and 22 per cent of the average prescription cost. The copayment would increase consumer participation in health care, constrain the costs of the ODB program, and presumably would not significantly reduce the use of appropriate and essential drugs. The impact of the copayment should be carefully assessed through well designed studies to ensure that quality of care is not compromised.

In estimating the effects of copayments, we allowed that the impact on use would be low or moderate until the cap was reached, at which point there would be no further reductions in use.

We estimate that the average annual costs of copayments for the seniors who pay would be between \$65 and \$90 a year, with no more than 10 per cent of the recipients reaching the \$250 cap.

It should be noted that physicians tend to write prescriptions for ODB beneficiaries to last 30 days. If larger quantities were prescribed, the number of prescriptions would be



Figure 9.3

**Impact of Copayments on Costs and Savings in Millions of Dollars**

Copayment	Consumer Impact	Decrease in claims	Costs to Consumer ODB		Savings for ODB
\$3.00	Low	11.5%	\$47.0	\$244.4	\$81.6
	Moderate	22.8%	41.4	212.6	113.4
\$4.00	Low	14.4%	57.9	223.8	102.2
	Moderate	28.6%	49.8	185.2	140.8

reduced and recipients could receive the same amount of medication with fewer prescription charges. This would reduce the costs to ODB and the paying consumer, but would have to be considered in the light of other factors such as the need for on-going monitoring of patients during drug therapy.

Low income individuals and individuals with chronic disease could also be asked to make copayments if they had incomes above the revised social assistance limits. Using the mid-range estimates of the effects of copayments per prescription, the average low income consumer would pay about \$35 per year if the copayments were \$3, and \$44 per year if the copayments were \$4. The mid-range estimate of the cost to ODB would be more in the order of \$95 million rather than the \$150 million if coverage was complete. The government could extend the coverage to include low income individuals and persons with high drug costs and introduce modest copayments for those not receiving social assistance; the money saved could offset the costs of extended coverage.

**9.2 The Committee therefore recommends that recipients of Ontario Drug Benefit plan benefits not on social assistance should be required to participate in the costs of prescriptions. Cost-sharing should be in the form of a fixed charge per prescription of not more than \$4. The maximum amount to be paid by the consumer for prescription**

**drugs in any given year should be \$250 and any drug costs above that amount should be completely covered by the ODB.**

The impact of the copayment on drug use should be carefully assessed through well designed studies.

**9.1.6.5 Coverage: A Summary of Options:**

Access, quality of care and cost constraint are countervailing forces in planning health care policy. To extend OHIP to cover all drugs in the ODB formulary as well as related dispensing fees would ensure universal and comprehensive access to drugs. Quality of care would be enhanced to the degree that the use of appropriate and necessary drugs is improved. The Ministry of Health would essentially pay for all prescribed drugs sold in the province and the dispensing fees of the pharmacists. Health insurance companies would either restructure their policies and fee schedules to cover extended health benefits other than drugs, or drop their plans.

A second option would be to extend ODB drug coverage to all persons who are either without third party insurance or have inadequate coverage for major drug expenditures. Cost-sharing by the consumer could serve to control government costs. The government would essentially fill the gaps left by current public and private policies. Consumers may seek to shift coverage from private to a public plan in order to improve coverage and perhaps

reduce the out-of-pocket expenses. Similarly, the private carriers may seek to restructure their plans so as to eliminate high risk cases.

The third option is preferred by the Inquiry: it is to continue private health insurance plans for drug costs and employ an income means test to cover all cases where costs pose barriers to consumers' use of necessary and essential drugs. Copayments could be required of all recipients not eligible for social assistance. This could be accomplished by basing the STEP program on an income means test rather the social assistance test that is currently employed. Under these arrangements the insurance companies may modify their plans to switch subscribers with high drug costs to the public plan, or the consumer with high drug costs may prefer the public plan to private coverage.

The fourth option is to make minor modifications to the present system. The first step would be to monitor the impact of the current STEP program to assure that it is meeting the needs of lower income individuals and persons with catastrophic drug costs. Copayments for persons not receiving social assistance would control the costs the ODB program.

### 9.1.7 Informed Consumer Choice

With respect to pharmaceutical care, individuals in Ontario can be viewed as "patients" and as "pure consumers." Recipients of health care services are generally regarded as patients who are dependent on physicians who diagnose and prescribe. The doctor-patient relationship is based on the authority, expertise and legal and professional rights and obligations of the physician as well as the needs of the patient, who can be somewhat dependent and passive in the encounter. In a similar vein, the patient goes to the pharmacist who dispenses the prescribed drug and arranges for payment in accordance

with the coverage the patient has for drug costs. The pharmacist may provide the patient with instructions for taking the drug and information on side effects, adverse reactions, and use with other drugs.

The pharmacist may be in contact with the physician for information or to inform the prescriber about possible problems or contraindications for the prescribed drug. In this sense, one can speak of the doctor-patient-pharmacist triad.

The consumer is also a "pure" consumer. With respect to prevention and health maintenance, individuals consume vitamins, minerals and other nutritional supplements in either recommended or mega doses or they may eschew dependence upon drugs or supplements. If there are allergies, sinus problems, migraine headaches or similar complaints, the individual may consume a variety of non-prescription medications or prescribed drugs.

If the person has as ongoing chronic problem or disabling condition, the consumer becomes involved in self-care and makes decisions about seeking and taking prescribed and non-prescribed drugs. In the case of acute episodes, the consumer decides at what point to seek professional care and how to respond to medical advice and the information provided by the pharmacist. In part, the response may be based on the ability to pay.

This section of the report looks at the individual as consumer and patient. In addition to exploring the issues of self-care and professional care, we examine the issues related to monitoring of pharmaceutical care received by the individual and policies related to the rational prescribing and dispensing of drugs.

**9.1.7.1 Self-care:** Results from the Canada Health Survey indicate that individuals use a variety of drugs, vitamins, minerals, nutrition supplements and other health products to

promote health and prevent disease. There have been extensive studies of the effects of mega doses of vitamin C to prevent and minimize the effects of colds and other afflictions, but most of the supposed preventive remedies and strategies have not been systematically evaluated.

Researchers have used health diaries to study symptoms that individuals experience daily and what they did about them. One can note that symptoms and complaints presented in the doctor's office are the tip of the iceberg. Most of the morbidity is found in the daily symptoms and problems for which individuals do not seek professional care. As Verbrugge and Ascione<sup>9</sup> report, the most common actions are to take prescribed or non-prescribed drugs, consult with relatives or friends, restrict activity and, lastly, to seek medical care. The actions taken are related to the frequency, duration, and severity of the symptoms.

Where attempts have been made to assess the appropriateness of self-care and self-medication by family physicians, the consensus appears to be that, by and large, self-care steps taken by "healthy" adults for common problems and complaints were appropriate.

**9.1.7.2 Professional Care:** When an individual comes to the physician as a patient, the customary procedure is for that person to present symptoms, complaints or questions for the physician to assess. Occasionally a patient may ask for a drug without discussing the underlying problem although, according to the physicians who participated in the survey by Williams and Cockerill, this happens relatively infrequently in practice (see appendices, volume II.)

The physician is responsible for managing the therapy of the patient. The patient may have preferences, or indeed may expect or demand

that a specific treatment modality or drug be prescribed. While physicians participating in the survey by Williams and Cockerill reported that this happened, fewer than 10 per cent reported that pressure from the patient is an important influence in the prescription of drugs.

Physicians are also subject to counter pressures. On one hand, they may counsel patients not to take a drug for a given problem; physicians in the survey report doing so about five times a week. On the other hand, there is pressure for the physician to do something by the end of the patient visit and about half the physicians in the survey indicated that they prescribed a drug occasionally when it probably was not needed.

Consumers go to pharmacies to have prescriptions filled and purchase non-prescribed drugs; they may or may not consult with pharmacists while they are there. Pharmacists surveyed reported that they spent about half of their time dispensing prescriptions, about 11 per cent of their time counselling patients, and 10 per cent of their time recommending and selling non-prescription drugs. There is also the prescriber-dispenser-patient triad mentioned earlier, and pharmacists report spending up to 10 per cent of their time contacting physicians about prescriptions and discussing the therapy of choice. The majority of the pharmacists surveyed approved having greater responsibilities in counselling patients and prescribers about drugs and non-drug alternative therapies. The role of the pharmacist is discussed in section 8.1 of the report.

**9.1.7.3 Education and Information about Drugs:** To determine the public availability of drug information, we asked a professor in the faculty of library and information science at the University of Toronto to survey public libraries, book stores, and articles in popular magazines.

<sup>9</sup> Verbrugge, Lois M. and Frank J. Ascione, "Exploring the Iceberg: Common Symptoms and How People Care for Them." *Medical Care*. 25(6): 559-569, 1987.



The Compendium of Pharmaceuticals and Specialties is commonly found in public libraries. Other reference books found in the library included **Joe Graedon's People's Pharmacy**, **Handbook of Non-Prescription Drugs**, and the **Ontario Drug Benefit Formulary**.

Book stores have special sections for health, and there were more than 50 titles in these sections. The most frequently encountered titles were **The Pill Book** by Silverman and Simon and **Understanding Canadian Prescriptions** by Smith. As expected, the selection of titles of popular books was much wider in the libraries than the book stores.

The listings in the **Consumer Health and Nutrition Index** indicate that the number of popular magazine articles on health care is voluminous.

An earlier survey for the health committee of the Consumers' Health Association of Canada showed that, in order of descending frequency, most consumers obtain their health information from health care providers, media such as popular magazines, newspapers, television programs, relatives and friends, health care organizations, public libraries and the local book stores.

Consumers are besieged with information about drugs through advertising of drug products and health maintenance strategies in articles and books, programs on the electronic media, and the information they receive from friends, relatives, and health care professionals. The information that is available may neither be the best, nor the most appropriate, for rational use by the consumer.

Education and information on drugs and their use may be directed toward providing the consumer with a general orientation or perspective on drug use. Alternatively, consumers may be given specific information on recommended drugs or strategies for self-care of specific health problems. Health

education in the schools could be structured to include information on the role of drugs in maintaining and promoting health and the use and abuse of drugs.

There have been innovative approaches to health education. For example, Time Stitches is a game for elementary and junior high school students wherein players have one hour to live unless they change their unhealthy lifestyles. The players are required to answer questions on drugs, drug awareness, nutrition, and general health. The Victorian Order of Nurses developed a game called Spinach, modeled after the game Trivial Pursuit. It is designed to help seniors anticipate changes that come with age and develop strategies for handling the changes. Questions are related to health care, including the use of drugs. Games and other strategies can be adopted by agencies for incorporation in programs for recreational and social services.

Drug manufacturers may advertise non-prescription drugs, but they are prohibited from direct public advertising of prescription drugs. They can use advertising to suggest that persons with particular problems should consult with their doctors, particularly if there is a drug product of choice that doctors are likely to prescribe for that problem. The relative importance or influence of advertising in shaping the decisions of consumers has not been determined.

Physicians and other health professionals have key responsibilities for educating consumers about drugs. Visiting nurses, pharmacists and doctors can review the drugs consumers have on hand and provide information on their appropriate use or disposal.

Health professionals are expected to advise consumers on drug and non-drug alternatives for the management of specific problems. For example, the consensus conference on non-pharmacological approaches to the management of high blood pressure has just released its guidelines for managing hypertension

through changes in lifestyles, nutrition and stress management and on how pharmacological and non-pharmacological measures can be combined in the prevention and treatment of high blood pressure.

Health professionals are also responsible for informing patients about drug therapies for managing specific problems. In addition to the instructions for taking medications, individual patients should be advised of possible side effects and adverse reactions. If there are alternatives to the drug therapy, patients should be informed of options so they can consider costs, side effects, and the effectiveness of the drugs. Tolerance to drugs, and psychological and physiological reactions to them, are major determinants of effective use and compliance.

By providing more comprehensive information on self-care management of health problems, health professionals can reduce reliance on medical care services and help contain costs.

## 9.2 Drug Utilization Review

Drug utilization review is one form of quality assurance of drug therapy which can improve the health of the public generally and individually. Our endorsement of reviewing drug treatments is based on the desire for more effective prescribing. Patient care should be given priority attention in a utilization review, which will allow problems of over- and under-prescribing, as well as malprescribing, to be addressed.

Increasing attention is being given to drug utilization review as a technique for evaluating effectiveness, costs and quality of drug prescribing. It also offers a method of promoting cost-effective drug therapy without sacrificing quality of care.

The literature is replete with articles and reports dealing with one or another aspect of drug utilization review. Many of them are purely descriptive; while they reflect the "state of the art" on drug utilization review, they seem to lack the theoretical basis upon which an appropriate process could be widely established. Importantly, virtually all fail to use a demonstrated effect on health as the major dependent variable of interest. Therefore, the goal of drug utilization review is to improve the **quality of patient care** through prescription and use of appropriate drugs, when their use, based on sound medical judgement, is indicated and when the cost associated with measurable effect on the health of individuals or groups of patients is acceptable.

Drug utilization review world-wide takes many forms—and is often interpreted to mean different things. We will not review these; far too often, the systems are set up to monitor cost with the standards of "care" being defined in dollars saved rather than in lives saved or health improved.

A drug utilization review must include information on four interrelated items. These are the **drug** (therapy), **patient** (diagnosis), **physician** (prescriber), and **pharmacy** (dispensing record.) At present, Ontario has no capability to conduct such drug utilization review. The Ontario Medical Association (OMA) has stated that it is willing to take the lead in developing demonstration systems at the local level that might be more generally applied.

Drug utilization monitoring must be linked to an audit of the patterns of prescribing. Physician peers and experts prepare relevant (e.g. local, national, etc.) auditable standards of rational prescribing for selected drugs and drug classes. An audit, using pre-agreed standards, then provides a way of identifying unacceptable deviations in prescribing practices. Information feedback strategies to individual physicians are coupled with general and targeted educational manoeuvres.

Specific programs can be developed to examine patient outcomes in target populations (e.g. institutional patients) and for target drug groups (e.g. neuroleptics) of special concern. The focus and duration of monitoring and audit can be varied, but preferably it should continue for a period which is sufficiently long to establish the effectiveness of each feedback and each step taken—educational or otherwise—to modify drug use. Typically, this may be for up to one year.

Extensive evidence exists that local and national drug utilization monitoring systems linking the drug and its actual use are essential if quality drug use is to be achieved (e.g. British Columbia Pharmacare, [Canada]; Medicaid Management Information Systems [USA]; Prescription Prescribing Authority [U.K.]). Many existing drug utilization monitoring systems, some quite small, can be used for this purpose. Local decentralized approaches are very desirable since they are more readily accepted and usually address real problems in a local setting. The accepted standard should be set by peers and experts.

With the advent of more comprehensive health care, the financial dimension of rational prescribing arises more and more. The extensive involvement of governments, insurers and health care administrations in drug distribution and use emphasizes the financial aspects of pharmacotherapy. Often drug utilization systems are concerned only with cost reduction. In such systems, standards for prescribing and determining interchangeable products are often formulated by health administrators and have little to do with quality patient care. Finally, compliance with guidelines should not substitute for direct measures of health status and outcome in patients.

Appropriate drug utilization review should improve patient care. It will, coincidentally, also prevent waste and save money.<sup>10</sup>

**9.3 The Committee therefore recommends that the Ministry of Health, in conjunction with Council of Faculties of Medicine, take the lead in developing, by 1992, pilot drug utilization review programs that can become an important part of continuing medical education. The goals of these projects would be to determine practical and effective ways of improving the quality of drug prescribing and the health status of patients. Such projects should be supported financially, at arms length, by the province. (See also recommendation 4.6.)**

An acceptable definition of what constitutes a medication error should be established. This will be necessary for effective drug utilization review.

### **9.3 Adverse Drug Reaction Reporting Program**

An adverse drug reaction reporting program is an important part of post marketing surveillance. In Ontario, an adverse drug reaction program was established in 1981, initially with federal government support. Reports are acknowledged, reviewed by a multidisciplinary committee, used when appropriate in the preparation of "The Drug Report," and forwarded to the Bureau of Prescription Drugs in Ottawa. Drug manufacturers are also informed when appropriate. It has been successful<sup>11</sup> and is currently continued as a public service by the OMA. However, economic restraints are threatening the continuation of the program.

<sup>10</sup> Carruthers, G., T. Goldberg, H. Segal and E. Sellers. "Drug Utilization Review: A Comprehensive Literature Review," Toronto, Ontario, 1987.

<sup>11</sup> Gowdey, Charles W. and Michael Brennan, "Addressing Drug Reaction Reporting Program of the Ontario Medical Association: the first three years," *Canadian Medical Association Journal*, 152(1):19-25, 1985.



Some method of funding an adverse drug reaction program, other than the charity of one profession, seems appropriate in 1990 in Ontario.

The OMA drugs and pharmacotherapy committee reports pertaining to the adverse drug reaction reporting program are based largely on information submitted on adverse drug reaction reporting forms. Each report describes a clinical event that took place in association with the administration of one or more drug products. These reports represent suspected adverse drug reactions, since an absolute cause-and-effect relationship is difficult to establish. As the total number of drug products prescribed is not known, and not all adverse drug reactions are reported, this information cannot be used to estimate the true incidence of adverse drug reactions.

Ideally, the OMA committee would like to be notified of all suspected adverse drug reactions, whether the reaction is well recognized, previously unreported, potentially serious or relatively minor.

The importance of reporting severe untoward effects is obvious, but minor adverse reactions can also be indicators of significant morbidity. The receipt of reports of well known or relatively minor events can assist in the identification of possible predisposing factors, or perhaps highlight a widespread prescribing problem, the recognition and publication of which may lead to improved pharmacotherapy. Two categories are particularly important. The first involves all suspected adverse reactions to new drug products. The second includes all reactions to drug products that are suspected of affecting the course of a patient's management, including reactions suspected of causing death, danger to life, birth defects, admission to hospital,

prolongation of hospitalization, necessity for increased investigation, and cessation or limitation of productive activity.

Problems suspected to be the result of drug interactions, altered patient response associated with drug product substitution, or suspected deficiencies in the quality of drug products, should also be reported.

Adverse drug reactions can be reported to the OMA by using standard reporting forms available from the OMA office or, if more convenient, on the practitioner's letterhead. Alternatively, reporters outside area code 416 may use the OMA's toll-free telephone line (1-800-268-7215) or FAX machine (416-963-8819) to transmit the details of a suspected adverse drug reaction. Start-up materials are available from the OMA office to assist hospital personnel in the introduction of adverse drug reaction reporting procedures in their institutions.

Suspected adverse drug reactions may be reported by all health professionals, including physicians, nurses, pharmacists and dentists, as well as medical technicians and medical records personnel.

A major problem with all adverse drug reaction reporting is the "tip of the iceberg" phenomenon in which only a small proportion of the adverse drug reactions that occur are actually reported. The Committee noted that in Ireland adverse drug reaction reporting was stimulated and increased 50 fold by paying a small fee for such reports.<sup>12</sup>

**9.4 The Committee therefore recommends that an Ontario adverse drug reaction reporting program be continued and that it should be supported by the province.**

<sup>12</sup> Feely, J., S. Moriarty, P. O'Connor, "Stimulating reporting of adverse drug reactions by using a fee," *British Medical Journal*, 500:22-5, 6716: 1990.

There is much merit in continuing the present OMA program with MOH involvement along the lines of the very successful collaborative laboratory proficiency testing program.

## 9.4 Misuse and Abuse of Prescription Medications

Broadly speaking, misuse of prescription medication is inherent in any use which is not in accordance with the directions and uses for which the drug is authorised or intended. This section of the report focuses on that area of misuse which is better termed abuse, including intentional incorrect usage. As we use the term, abuse implies some sort of illegal or dangerous use, and includes the use of prescription medication in addictive situations. Abuse represents a specialized area of non-compliance, which involves the risk of negative clinical consequences and where the outcome can even be life-threatening. It requires solutions which deal with more than just misunderstanding or miscommunication.

The majority of the problems which have been the subject of research and discussion have involved mood-altering drugs, generally termed psychotropics. Included are most of the medicines which affect the central nervous system: barbiturates (highly addictive and not commonly prescribed now as sedatives), narcotics (even more addictive and generally used only for the control of severe pain); the major tranquillizers (anti-psychotics); anti-depressants; amphetamines (stimulants and appetite suppressants); and benzodiazepines (the so-called minor tranquillizers). The benzodiazepine products and the barbiturates are also referred to as the sedative/hypnotic group. Because of their sedative effects, some antihistamines also fall

within this group. The psychotropics which are most commonly abused are barbiturates, narcotics, benzodiazepines and amphetamines.

There are also abuse problems associated with drugs for other kinds of behaviour difficulties, such as diuretics, laxatives and emetic drugs which are used by persons with eating disorders. However, with the exception of the stimulants, most of those abused substances are over-the-counter medications and, strictly speaking, lie outside the mandate of this Inquiry. A final area of abuse involves substances—most notably anabolic steroids—taken to enhance athletic performance and improve physical appearance.

### 9.4.1 Mood-altering Drugs

Much of the information contained in the following description of the problem as it exists in Ontario with respect to misuse and abuse of psychotropic drugs comes from the brief presented to the Inquiry by the Addiction Research Foundation.<sup>13</sup>

The use of prescribed psychotropic drugs has potential negative clinical consequences, including adverse drug reactions and interactions, use for non-medical purposes, overdosage, and the major problem of development of drug dependence. These consequences are, of course, not inevitable but the risk/benefit equation is often unfavourable. The health hazard inevitably associated with the use of these products contributes to great human misery, to increased health care costs, and to increases in crime and social disruption.

<sup>13</sup> Addiction Research Foundation of Canada, *Clinical Problems Associated with the Use of Prescribed Psychotropic Drugs*, November 3, 1968.

## 9.4.2 Dependence on Drugs

One of the major areas of concern surrounding the use of psychotropic drugs is the dependence upon them which frequently develops; individuals who have had medication prescribed for a long period of time for the legitimate treatment of symptoms or conditions are particularly at risk. Symptoms include anxiety, panic attacks, depression, insomnia and chronic pain. Generally, the drugs involved are the minor tranquillizers, sedatives/hypnotics and the opiates. Statistically, this population group is largely middle-aged, although there is an important sub-group composed of elderly patients who may get these prescriptions from more than one physician, and who are at particular risk for adverse drugs effects because of their age-related increased physiological and central nervous system sensitivity.

A second large group of individuals which may become dependent upon this group of drugs are persons who are also dependent upon alcohol. The physicians who prescribe these products for symptoms associated with alcohol abuse may or may not be aware that the patients' symptoms or problems are alcohol-related. The result is cross-dependence involving both alcohol and drugs.

Finally, there are individuals who use these drugs for non-medical purposes, obtaining them directly from physicians or on the street. Sometimes these persons use the prescription medication as their abused 'drug of choice'; sometimes prescription drugs are used as substitutes when illegal drugs are not readily available.

Overdose problems occur most commonly among members of these three groups of chronic abusers of prescription medication.

There are, however, the additional problems of suicide attempts by individuals who are not chronic users, and of accidental ingestion, usually by children.

## Factors Contributing to Abuse

**9.4.3.1 Levels of Use:** There is a direct connection between the levels and types of medication being prescribed in a community, and the level of prescription drug abuse.<sup>14</sup> The risk of abuse is therefore higher in those groups which have higher utilization rates of drugs legitimately prescribed by physicians and dentists. The results of Canada's Health Promotion Survey<sup>15</sup> reveal that sleeping pills and tranquillizers are used at higher levels by older individuals; the use of sleeping pills increases sharply with age, with one in five Canadians 65 and older having used them within the 12 month period prior to the survey.

Usage levels are also higher among older women (23 per cent), francophone women (14 per cent), retired men (20 per cent), retired women (21 per cent), women keeping house (12 per cent), and people in the lowest income category (13 per cent). Although tranquillizer use is generally lower than sleeping pill use, the same groups are generally the high users of both. For example, 12 per cent of people 65 and older use tranquillizers, as do 13 per cent of francophone women, 14 per cent of retired women and nine per cent of retired men. Of larger concern is the high level of recorded combined use of both sleeping pills and tranquillizers, used by 8 per cent of retired persons, 9 per cent of separated or divorced women, and 8 per cent of widows.

<sup>14</sup> Busto, U., et al. "Psychotropic Drug Utilization in Canada: Implications for Drug Abuse Liability."

<sup>15</sup> *Canada's Health Promotion Survey*, Health and Welfare Canada, 1988.



There is reason for great concern about the group with the highest utilization rate: the elderly. "Although psychotropic drug use among the elderly living outside institutions does not appear to be a significant public health problem, evidence suggests that once a person in this age group begins to use a psychotropic drug, there is a reasonable chance of misuse—that is, of long-term continuous use."<sup>16</sup>

"Analysis of users of anti-anxiety drugs revealed that long-term use (defined as regular daily use for a year or longer) was relatively rare, occurring among 15 per cent of all such users...only 1.6 per cent of all surveyed adults...18...[to] 79...,"<sup>17</sup> but "A third of all the long-term users were 65...or older," and in terms of general use of psychotropics "in the group 65 years and over, female use exceeds male use by almost 60 per cent."<sup>18</sup>

Other identifiable groups are also at high risk of abuse because of the high levels of prescribing. These include the chronically ill, the majority of whom are also elderly. In a study of a group of chronically ill elderly, it was found<sup>19</sup> that about one quarter were prescribed psychotropic drugs, and 27 per cent of that quarter were on two or three of them simultaneously.

**9.4.3.2 Consumer Demand and Social Expectations:** Consumers view psychotropic medications as they do other prescription medications: with the belief that there is a pill for every ill. Many in our society do not believe that they should put up with any symptom if relief is available, even if the relief is of short duration and the risk of long term drug dependence is high. It has become almost axiomatic that if one is in emotional or physical pain or distress, relief should be

available, often in the form of a pill. As consumers become more knowledgeable about psychotropic drugs, they are demanding specific forms and types of therapy for their own and relatives' ills.

A Health and Welfare Canada publication put the problem this way: "...we question whether many of the problems of living presented to physicians can be addressed by the health care system at all. Although recognising the value of benzodiazepines in short-term care, their use poses serious questions regarding interference with individual's abilities to alter their lives and thus cope with stresses without the aid of chemicals.

"Given the large number of Canadians currently using benzodiazepines, the possibilities of impaired decision-making, decreased learning skills, released aggression and impaired ability to empathise have a significance extending beyond the lives of these individuals to the community at large."<sup>20</sup>

**9.4.3.3 Pharmaceutical Manufacturers:** Manufacturers understandably want to sell their products and a major marketing strategy involves identifying all potential uses for a product and convincing physicians to prescribe their products specifically for each of those uses. The result of this strategy in the area of psychotropic medications has been the extension of their use, legitimately or not, to "solving" the stresses of life. Unfortunately, this type of prescription "solution" rarely does more than provide temporary or inadequate relief. In the worst situations, the problem of drug dependence is added to the problems of living for which the drugs were taken in the first place.

<sup>16</sup> Lipton, H.L., "Drugs and the Elderly: Clinical Social and Policy Perspectives, *Stanford University Press*, 1988.

<sup>17</sup> Ibid. p.30.

<sup>18</sup> Op. cit. p. 32.

<sup>19</sup> Achong, M.R., J.R.D. Bayne, L.W. Gerson, S. Golshani, "Prescribing of Psychoactive Drugs for Chronically Ill Elderly Patients," *Canadian Medical Association Journal*, 118(12): 1503-08, 1978.

<sup>20</sup> Health and Welfare Canada, "The Effects of Tranquilization: Benzodiazepine Use in Canada."

**9.4.3.4 Physician Prescribing:** Physicians' prescribing patterns depend upon various factors, including their age and the prescribing views which predominated during the period of their medical education (see chapter 7). They are also influenced strongly by the contacts they have with manufacturers' representatives, by their colleagues, and by their patients. Physicians may succumb to the pressure to give patients some sort of assistance, even if the result is an unwisely-prescribed psychotropic drug. "As patients bring more and more psychosocial problems to the physician, there is need for both physician and patient to have these problems considered as legitimate medical issues."<sup>21</sup> However, the Inquiry believes that alternatives to drug therapy should be given priority.

Patients who abuse drugs and/or participate in illegal diversion of drugs are often also expert at feigning legitimate medical problems. There are, finally, always some few physicians who are willing participants in this illegal prescription drug traffic, whether for financial gain or because they have substance abuse problems themselves. Prescribers who inappropriately "self-medicate using narcotics or controlled drugs can have their prescribing privileges suspended."<sup>22</sup>

#### 9.4.4 Illegal Use of Prescription Drugs

In addition to the unfortunate abuse of addictive medications through the carelessness, negligence or even collusion of a small number of prescribers, there is a growing problem related to the illicit diversion of prescription drugs. The Royal Canadian Mounted Police (RCMP), the Ontario Provincial Police (OPP) and the Metropolitan Toronto Police all report an increase in the

number and type of prescription drugs diverted for street sale and illicit use.

"National trend indicators point to a serious and escalating problem of diverted licit pharmaceutical drugs from medical sources which has brought heightened concern to law enforcement authorities across the country."<sup>23</sup> "Drugs are diverted in a number of ways: break and entry or armed robbery; transit losses; fraudulent prescriptions; multiple doctoring; excessive or inappropriate prescribing by practitioners; personal use by health care providers; etc."<sup>24</sup> The RCMP indicate that illegally obtained street pharmaceuticals are increasingly coming from sources such as double and multiple doctoring,<sup>25</sup> and through the active participation of a small segment of the medical community.

The Bureau of Dangerous Drugs of Health and Welfare Canada has estimated that in 1987, 300,000 pills were illegally obtained in Ontario through theft, robbery, forged prescriptions and unexplained losses. The street value of these drugs has been estimated at \$3.5 million. The illegal or unethical use of prescription drugs—particularly anabolic steroids—in sports has been the focus of the federal commission headed by Dr. Justice Charles Dubin. Testimony before the Dubin Commission, and information received by this Inquiry from the RCMP, confirm that anabolic steroids are readily accessible in sport and fitness facilities, and have been in widespread use in both amateur and professional athletics. They are distributed illicitly, having been imported from other countries, illegally manufactured in Canada, or illegally diverted from stocks held by pharmacists and physicians.

<sup>21</sup> "Controversies in Therapeutics," Monograph, Philadelphia: Saunders, 1980.

<sup>22</sup> Brief #161-3000, Royal Canadian Mounted Police (The Commissioner).

<sup>23</sup> Ibid., brief #161-3000.

<sup>24</sup> Health and Welfare Canada, brief #171. This submission also expresses the concern that quantities per theft incident have been on the increase because pharmacies are carrying larger quantities of narcotic drugs in their inventories.

<sup>25</sup> Health and Welfare Canada indicates a five-fold increase in convictions for double doctoring over the past five years.

Another problem identified by the RCMP is the clandestine manufacture of pills, specifically intended for street use, which are designed to resemble familiar legal drugs, such as varieties of diazepam (i.e. valium) and methaqualone.

Federal, provincial and municipal police forces are attempting to cope with this problem by focusing on both the demand and supply factors. Traditional police activity is directed to reducing supply. In the short run, this is the best way of restricting the illegal use of drugs, but its limitations are obvious. Vigorous police activity in many countries has failed to halt the increase in this dangerous activity. In Ontario, the illegal use of prescription drugs is largely, though by no means exclusively, an urban phenomenon. As might be expected the problem is greatest in the Metropolitan Toronto area. Accordingly, the Metropolitan Toronto Police force is currently expanding the number of officers assigned to drug squads and a prescription squad is being established.

Stonehenge Therapeutic Community, which treats substance abusers, including those who abuse prescription medication, made four observations: "1) Double or multiple doctoring is a common practice among substance abusers. 2) The female substance abuser is more likely to employ double doctoring and prescription forgeries to illicitly obtain licit drugs than is the male addict. 3) There is an apparent lack of awareness concerning double doctoring among some physicians combined with a complacency concerning the security of prescription pads and drug storage units. 4) Due to the covert nature of illicit pharmaceutical drug abuse and the possible judicial repercussions to the abuser...present statistical information is inadequate, under-reported and tends to minimize the actual frequency of

double doctoring occurrences in this province."<sup>26</sup>

Recommendations from the Metro police regarding prescriptions included utilization of non-photocopiable paper for prescription pads, writing prescriptions in full, using both numerals and written amounts to avoid changes, numerical coding and indexing,<sup>27</sup> triplicate prescriptions for "at risk" drugs, and provision of a telephone listing of doctors to enable pharmacists to run quick checks. With respect to thefts and break-ins, they recommend installation of cameras and alarms, vaults for narcotics, increased safety standards for pharmacy licensing, and visible posting of security measures. With respect to education, they recommend ongoing liaison among the police, the College of Physicians and Surgeons of Ontario and Health and Welfare Canada, programs to demonstrate identified "scams" to physicians and pharmacists, and accountability for prescription pads. Stonehenge made a similar recommendation with respect to the education of health care workers on the specific "scam" of double-doctoring, and called for greater accountability, particularly with regard to prescribing and dispensing of psychoactive substances.

The RCMP also recommended prevention, achieved through education and increased awareness: "Law enforcement prevention/training programs directed to law enforcement agencies, physicians, pharmacists, health administrators and other relevant parties involved in active or potential intervention, should address such issues as: defining the nature and extent of the diversions problem; identifying factors which encourage and foster dependence and the misuse of pharmaceutical drugs; the phenomenon of displacement to other drugs (i.e. the connection between heroin availability and

<sup>26</sup> Stonehenge Therapeutic Community brief #77.

<sup>27</sup> This was also the recommendation the OPP submission, which suggested sequentially pre-numbering prescriptions so they could be traced from the physician, through to the patient and finally to the pharmacy. Sequential numbering allows pharmacists to be alerted if a numbered pad of prescriptions has been stolen. The OPP also made recommendations about non-photocopiable paper, alarms, and physician and pharmacy education about scams.



abuse of diverted pharmaceuticals); double/multiple doctoring; and the development of prescription user profiles. Of course, it is without question that primary prevention must include educating youth and parents alike on the potential dangers and repercussions that may result from the misuse and abuse of licit pharmaceuticals.”<sup>28</sup>

Metro police recommended that examples of specific active prescription forgeries be published and distributed to all pharmacies in an area, perhaps through local newsletters. The OPP recommended stiffer penalties for double doctoring and selling Schedule F drugs.<sup>29</sup>

Many groups<sup>30</sup> encourage the increased education and awareness of physicians about community drug treatment resources. The Bureau of Dangerous Drugs of Health and Welfare Canada recommended pooling of relevant prescribing and utilization information, education of practitioners about drug abuse, and development of methods to deal with the problems associated with large inventories of psychoactive drugs. However, all three police forces believe that only measures that reduce demand will prove to be significantly effective in the long run. For example, the Metropolitan Toronto Police force has also decided to assign more officers to community drug education programs.

This Inquiry agrees that the objective must be a change in public attitudes toward drug use. Clearly, however, responsibility for educating the public, and especially young people, regarding the dangers of misusing and abusing drugs cannot be assigned primarily to the police. Vigorous, ongoing public education programs involving our schools, the media, our three levels of government, industry, labour and community groups, are required. It is as important to persuade the public not to take powerful medications needlessly as it is

to persuade people not to smoke. Indeed, the success of anti-smoking campaigns in changing public attitudes provides reason for hope that a similar effort directed against the abuse of drugs might be effective.

**9.5 The Committee therefore recommends that the governments of Canada, Ontario and the municipalities set up appropriate mechanisms, properly funded and supported, to reinforce the social unacceptability of drug abuse.**

#### **9.4.4.1 Prescription Forgery and Fraud:**

Some prescription drugs, especially narcotic and mood altering medications, have significant resale value on the street. Such illicit use of prescription drugs can be minimized by the use of an innovative “triple prescription system” like that in use in Alberta. We are not persuaded that the cost of such a program in Ontario would be justified by the advantages. We believe that many of the benefits can be obtained when prescribers and patients are each identified by a unique identifier, as we had recommended in an interim report. Both patient drug profiles and prescriber profiles will then be available. Out-and-out forgery seems relatively rare, but clearly prescription pads need to be kept in reasonably secure places.

**9.4.4.2 Prescription Drug Addiction:** There is evidence to support the widespread perception that hypnotics and sedatives are over prescribed as judged by the content of very many organizational and individual submissions to the Inquiry. Many submissions made the point that this was a particular problem for the elderly.

It is very easy for prescribers to start hypnotic, sedative and tranquillizing drugs but it may be very hard for patients to stop them. Expensive and distressing confusional states, depression

<sup>28</sup> Royal Canadian Mounted Police brief #161.

<sup>29</sup> The Food and Drugs Act and Regulations, with amendments to April 1, 1977. This is the schedule containing prescription drugs.

<sup>30</sup> Stonehenge Therapeutic Community, brief #77.

and falls are all too often the result. Psychological and sometimes physical dependence occurs all too often. The Inquiry was very impressed by a simple and effective way of dealing with this problem that was presented to us in Ottawa by Dr. Cohen, a family doctor. His approach is positive and non-judgemental and involves requesting second opinions prior to prescribing sedatives for long-term use.<sup>51</sup> Review of sedative use is, of course, part of the general review of treatment that should be a routine part of rational pharmacotherapy (see chapter 7). Clearly prevention is better than treatment and the Committee suggests (see recommendation 11.5) that prescriptions for hypnotics, sedatives and tranquillizers be for the shortest possible time and be clearly marked "no repeats."

We recognize that in rare instances patients with severe, long term anxiety states may require long term sedation.

**9.6 The Committee therefore recommends that the Ontario Medical Association, the College of Family Practice and the Addiction Research Foundation should jointly research the various approaches to reducing the overuse of hypnotics, sedatives and tranquillizers.**

## **9.5 Nursing Homes and Homes for the Aged**

In 1988 there were 181 homes for aged persons with 28,870 beds. The beds are divided into two categories, residential care (13,630 beds) and extended care (15,240 beds). Extended care is for aged persons who require at least 90 minutes of skilled nursing per day.

There are 264 nursing homes in the province with 24,800 beds. The issues and problems in pharmaceutical services are discussed in the context of nursing homes, but they apply as well to homes for the aged.

There are two sources of drugs for patients in the homes: non-prescription drugs are ordered in bulk through Government Pharmacy and kept in stock in the nursing home; medications prescribed by the patients' physician are dispensed in a pharmacy and delivered to the home. The costs of the drugs are paid directly by the ODB.

The Ontario Nursing Home Association (ONHA) submitted a brief outlining the issues and problems related to drug therapy for patients in nursing homes. The process involves the following steps: physicians' orders, medication ordered through pharmacy, receipt of medications including the recording of information in a drug record book, administration of medications, reordering of medications, preparation of medications for leave of absences, the handling of narcotic drugs, medication review, and the destruction of medications. Nurses are generally responsible for the administration of medication. The number of beds per registered nurse ranges from 60 to 80. The ratio of residents per physician ranges from 10 to 50, with most physicians having only one or two patients per facility. The drug utilization rate on average ranges from six to eight drugs a day; half of these are non-prescription drugs. Most prescriptions are re-ordered monthly by the physician. The major thrust of the brief involved the time and responsibilities of the nurse for managing the medications in the nursing home.

<sup>51</sup> Council on Aging of Ottawa-Carlton, brief.#118-3100; Dr. Cohen made a presentation in Ottawa at the public hearing.

In 1986, the College of Nurses of Ontario and the Ontario College of Pharmacists jointly struck the task force on provision of medications by health care services. The report differentiated between dispensing and administering drugs. The dispensing function was thought of in terms "of removing medication from a labelled container and placing it in another properly labelled container for distribution to a patient." Administration is the act of removing the drug from the labelled container and administering it to a patient. The Health Disciplines Act requires that dispensing must take place in an accredited pharmacy. However, public hospitals, nursing homes, homes for the aged, and other residential care facilities are exempt from this regulation. Even though it is not part of the scope of practice for registered nurses to dispense drugs, there are no legal barriers to dispensing drugs in health or custodial institutions. The task force recommended that the dispensing of drugs in facilities be reconsidered. It recommended that wherever possible the pharmacist be responsible for the dispensing functions. Where pharmacists are not available, it recommended that registered nurses dispense drugs in accordance with policies and procedures set out by a pharmacy and therapeutics committee.

Nursing homes and homes for the aged do not have pharmacists on staff; they obtain services from pharmacies in the community. Pharmacy payments can be organized through three mechanisms of payment. Shoppers Drug Mart, which provides services in long term facilities, provided an analysis of its experiences with the various payment mechanisms. It provides two categories of services: packaging and distribution and clinical consulting.

Drugs have to be packaged for simple, accurate and safe administration, such as the carded dosage system. The staff of the homes prefer to have the non-prescribed drugs packaged along with the prescribed medications, even though most of these drugs are obtained

from Government Pharmacy. Distribution involves delivery, after-hour service, and special equipment to facilitate distribution such as medication carts and facsimile machines which they provide for the facilities.

Clinical consulting activities include entries in the drug record book, drug reviews for the residents, in-service education for residents and staff, monitoring of the drug distribution system, quality assurance inspections and audits, participation in drug and therapeutics committees, conferences with physicians and nurses, and the destruction of surplus drugs. Shopper's Drug Mart estimates that good clinical consulting results in an average reduction of 0.7 drugs per day per resident. Based on experience, it has found that the average number of prescriptions per resident is 4.1 in facilities with clinical consulting and 3.4 in facilities without clinical consulting. It also points out that under the ODB, there is no compensation for these activities above and beyond the dispensing fee.

The reimbursement systems for long term care facilities vary by province. Pharmacists in British Columbia and Manitoba are reimbursed for the acquisition cost of the drug and a capitation fee per month for each long term care bed served. In British Columbia there is a sliding scale based on the size of the facility. The fee is \$25.50 per bed for facilities with fewer than 200 beds, which decreases to \$14 per bed in the largest facilities, which have 800 or more beds. In Manitoba, the standard fee is \$24.50 per bed, regardless of the size of the facility. Chronic care facilities in Metropolitan Toronto pay a capitation fee of \$30 per bed per month for pharmacy services.

In the other provinces pharmacists receive reimbursement and a standard dispensing fee, and all provinces, save Prince Edward Island and Nova Scotia, allow for a mark-up on the cost of the drugs. It is the contention of Shopper's Drug Mart, and other pharmacists presenting information to the Inquiry, that the



dispensing fee neither includes the cost of packing the drugs purchased through Government Pharmacy, nor the consulting activities. They believe that the rate of return on pharmacy services for long term care facilities is unacceptably low. It is their contention that pharmacists serving long term care facilities subsidize the value-added services from other earnings. Shopper's Drug Mart proposed that a \$4 consulting fee per bed per month should be added to the reimbursement scheme for pharmacies serving long term care facilities. In the preceding chapter, the Inquiry recommended (8.16) that payment mechanisms be examined which would reward the provider of pharmaceutical services and be independent of the status or dispensing of a drug. The payment mechanisms for pharmacists who serve long term care facilities should be examined and reconsidered.

The co-operation and active participation of physicians and nurses are required for the pharmacy consulting services to be effective. Consulting pharmacists free the nurses of time and responsibilities in the administration of medications, so there are incentives for the nurses to be involved. From the discussions with nursing home staff and pharmacists, it appears that it is more difficult to gain the active participation of physicians on drug and therapeutics committees in long term care facilities than in acute care hospitals. It should be noted that physicians are not paid for committee participation and other activities directed toward the improvement of quality of care. Physicians may feel less inclined to contribute time when they have only one or two patients in the facility, as is the case in most instances. As noted in recommendation 8.19, pilot projects for drug therapy committees should be tested for long term care facilities.

Surplus prescribed drugs are those in containers labelled with the name of a resident whose drug therapy has been changed, who has died, or who has been transferred or discharged from the long term care facility.

The nursing home regulations permit the reallocation of previously dispensed drugs within the home and set out labelling and other requirements for this process. This procedure must be on the direction of a prescriber and under the direct supervision of a prescriber or pharmacist.

The administrative costs of reallocation are high. The costs and savings of this policy are unknown. The task force on provision of medications by health care facilities considered these issues and called for a complete study of the cost and benefits of reallocation of drugs. To the best of our knowledge, their recommendations were not acted upon.

Legislation in Ontario prohibits the return of drugs to the pharmacy to be recycled, packaged and dispensed. Recycling of drugs is permitted in British Columbia and Manitoba. It is the contention of Shopper's Drug Mart that the recycling of drugs in the pharmacy would save time, money, and reduce the amount of drugs that have to be destroyed.

The regulations provide for the destruction of surplus drugs under proper supervision. In a study of three facilities by Extendicare in 1986, the average annual cost of drug destruction was \$39.34 per resident. Shopper's Drug Mart estimated that 25 per cent of the consulting pharmacist's time was spent supervising the destruction of drugs.

Pharmaceutical services are a vital part of the services provided in long term care facilities. The patients are old, have major health problems, and frequently are unable to manage their own medications. As noted, they take a number of drugs daily. Questions have been raised about the adequacy of current policies and mechanisms for assuring that drugs are prescribed and dispensed appropriately. These issues are addressed in chapter 11.

## 9.6 Special High Risk Groups

There are persons with particular diseases, disabilities or conditions that require expensive and prolonged drug therapy. Some of these special problems are currently being addressed by specific provincial drug plans, such as the cost of antituberculous medication, cyclosporin for transplant recipients and AZT for AIDS sufferers. The Inquiry considered two groups with high cost drug therapy for life-extending drugs whose costs were not covered by a drug plan: those suffering from cystic fibrosis and from thalassemia. There are other high risk groups whose drug costs are basically covered but who may be at risk with respect to the quality of care they receive. Two such groups are psychiatric patients and residents of long term care facilities.

### 9.6.1 Cystic Fibrosis and Thalassemia

Cystic fibrosis (CF) and thalassemia are both inherited genetic disorders which require ongoing treatment; costs for drug therapy differ from individual to individual, but generally are very high. As a result of scientific advances, life expectancy and quality of life for sufferers from these conditions have been increasing over the past few decades. For example CF patients now have an average life expectancy in their mid-twenties, whereas it was only four years in 1958. This recent increase in life expectancy has resulted in the anomalous situation of adult patients being treated at clinics that until recently were located only in children's hospitals. For the most part, existing programs for the chronic treatment of these conditions are limited to persons under 18, since few or none of the patients lived beyond this age until recently.

Life-preserving drug therapies for these conditions have become more effective, but also more costly. Further, because of

increased effectiveness, more treatment can be given on an out-patient basis. One result of these trends is that clinics in children's hospitals have been transferring these costs to the patient and the patient's family, or to general hospitals which have no funded programs for these conditions. There has also been inconsistency in the way drug therapy costs are borne across the province on a patient-to-patient basis.

The Committee finds it unacceptable that access to needed drugs for these persons depends upon their financial status, and believes that access should be guaranteed without the imposition of excessive financial hardship. The affected person or family should not have to prove financial need in order to receive a life-preserving benefit. The Committee therefore made the following interim recommendations:

**9.7 That drug products and other medically indicated drug-related therapy (such as necessary enzymes and vitamins) used in the treatment of cystic fibrosis be funded as benefits under the appropriate Ministry of Health program.**

**9.8 That drug products and medically-related supplies used in the treatment of thalassemia be funded as benefits under the appropriate Ministry of Health program.**

As is the case with the previous recommendations, the Committee did not recommend the specific procedures by which these recommendations were to be implemented.

The number of Ontario residents affected by these recommendations is very small. There are approximately 860 CF patients now in Ontario, of whom about 300 are over 18 years of age. The estimated incidence is one in every 5,000 births, or 25 new cases of CF per year. There are approximately 125 diagnosed thalassemia sufferers in Ontario, 25 per cent

of whom are over 18. The incidence is one in every 20,000 live births, or roughly seven new cases per year.

While the cost of drug products, medically indicated drug-related therapy and medically-related supplies varies from person to person, a cost estimate of approximately \$25,000 per year for thalassemia sufferers and \$2,500 for CF sufferers seems to be reasonable. It is highly likely that new drug therapies to further increase life expectancy and quality of life for these persons will be introduced, and these can be expected to be very expensive. Unless these new drugs also prove to be useful for other more common problems, their costs will not fall much over time because few economies of scale will come into play and they are likely to remain single source drugs.

At the estimated annual cost of approximately \$25,000, it would take just over \$3 million each year to provide the estimated 125 thalassemia patients in Ontario with all the required materials, with a quarter of the costs being for adults over the age of 18 years. However, because not all patients comply with recommended drug therapy, and because some are already receiving benefits from the Ontario government, the increase in the MOH budget will likely be less than the \$3 million.

There are wide variations in the costs of formulary and non-formulary drugs for CF patients. We have received estimates from a number of sources which ranged from just over \$2,000 per year to about \$8,000 per year. It may well be that the costs of the medications and nutritional supplements are greater for adults than for children. Assuming that the average cost per patient was \$2,500, the projected costs for coverage would be \$2,150,000. Again, this does not represent an absolute increase in the costs to the MOH, in that about 30 per cent of the patients in the Hospital for Sick Children clinic are already

covered under the ODB plan. If this percentage holds true for all 860 patients in Ontario, then \$645,000 of the estimated annual amount is currently covered by the ODB program.

Many emotional and social benefits would result from the implementation of these recommendations. Not only would the patients and their families be relieved of the emotional burden that accompanies financial hardship, many people who are otherwise able to work would no longer be forced to rely on welfare to pay their drug bills. This should result in a small reduction to the overall provincial budget due to the removal of these individuals from the ranks of welfare recipients, as well as a boost to the independence and self-esteem of affected persons.

## 9.6.2 Psychiatric Patients

In 1988 the 10 public psychiatric hospitals in Ontario had 4,831 beds and 10,781 patients were discharged from care. There were 65 general hospitals with 2,229 beds in psychiatric units, and 38,868 patients were discharged from these units during that year. In addition, there were eight other psychiatric hospitals with 1,003 beds and 6,811 discharged patients. No estimates were available of the number of chronically mentally ill persons under physician care in the community, or of those with emotional problems who were in hospital but were admitted with other than psychiatric diagnoses.

There are three issues related to drug care in psychiatric units: 1) chemical treatment of patients who were legally determined to be mentally incompetent to make decisions; 2) informed consent for treatment; and 3) drug coverage for psychiatric patients in the community. The psychiatric patient advocate office was introduced as a quasi-legal program of the MOH, and there are offices in each of the 10 public psychiatric hospitals; they counsel about 62 per cent of the patients.

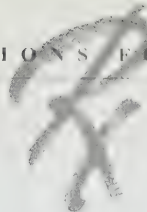


In 1987/88, there were 423 patients judged incompetent to consent to or refuse treatment. Incompetent patients have little choice in the treatment they receive. Other patients in the public psychiatric hospitals are to be fully informed about proposed therapies and consent to the treatment that is prescribed. Most of the pharmacies have unfilled positions, and neither the physicians nor the pharmacists have sufficient time to fully inform patients about the drugs recommended for treatment or to fully instruct them about the use of the medications.

About one-quarter of the counselling activities of the psychiatric patients' advocate offices pertain to the rights of the patients in therapeutic decisions. In practice, competence of the patient only becomes an issue if the patient refuses treatment. The more invasive and toxic the effects of the treatment, the more likely the patient is to refuse. Patients may have to choose between coping with the symptoms of their disorder or the side effects of the medication. If the patient is judged incompetent to make the decision, it must be determined who will represent the interests of the patient. In the case of the psychiatric patients' advocates office, the treatment staff have expressed concerns that counselling to inform patients of their rights interferes with the treatment process. The goal is for the staff and the counsellors to work together to reconcile any conflicts between rights and treatment so that the patients fully understand, agree to, and receive optimal therapy.

The costs of drugs are covered for psychiatric patients in hospital and the hospital covers the costs of drugs of their patients who attend outpatient clinics. Any patient who has been admitted into a psychiatric hospital may take a prescription for psychotropic drugs to a psychiatric hospital to have the drug dispensed. This has led to patients demanding that prescriptions for non-psychotropic drugs also be dispensed, as they are essential for their well being, and pharmacies in the psychiatric facilities have started carrying a wide stock of drugs as there are some questions as to the policy they should pursue.

Patients who obtain drugs through a community pharmacy have to have third party coverage or pay the costs themselves. If they are disabled by their illness, they undoubtedly receive social assistance and have ODB coverage. Other chronically mentally ill individuals are likely covered by the extension of the benefits under the STEP plan of the Ministry of Social and Community Services. The number of individuals who have large drug bills related to treatment, who are not covered by ODB or private health insurance plans, is unknown.



## Chapter X

### Alternative Therapies

*While the Committee was not asked to look at alternatives to prescription drugs, a number of submissions called attention to this issue. The Inquiry does not attempt a systematic examination of alternatives but concludes that such a study, conducted in accordance with accepted scientific standards, is merited in some areas.*

#### 10.1 Alternatives to Prescription Drug Products

In 1987 three significant reports relating to health care were issued.<sup>1</sup> All emphasized the key roles of health promotion and disease prevention. The Evans report addressed the role of the individual consumer in making healthful lifestyle decisions. The Podborski report called attention to the importance of adequate nutrition, exercise and recreation in promoting health, and of eliminating smoking and alcohol and drug abuse in preventing illness. The Spasoff report, in recommending health goals for Ontario, also emphasized the need to encourage behaviours that support health. Drawing on these reports and on a vast, worldwide literature that supports their recommendations, the Premier's Council on Health Strategy last year outlined strategic objectives for the province.<sup>2</sup> The first objective is to shift the emphasis in health care from treatment after the fact to health promotion and disease prevention.

These reports have in common an appeal to all Ontarians to look beyond the traditional health care services to what they themselves can do to remain healthy. Traditional services offered by Ontario's extensive system of

hospitals, home care services, clinics and private professional offices are mostly geared to treat illness once it occurs. Increasingly, it is recognized that Ontarians have a responsibility to do what they can to protect their health and to prevent illness.

Prescription drugs do not specifically accomplish this aim. Drugs primarily help patients who are already sick or are at risk of becoming sick. Powerful drugs are especially useful for those persons who have acute illnesses or are faced with life threatening conditions, as discussed in chapter 2. However, the majority of prescription drugs are now used to treat chronic conditions, many of which do not immediately threaten life or functioning. Many drugs are prescribed for ongoing symptom relief. Yet drugs are, of course, not innocuous; the reason some require a prescription is that, as chemicals foreign to the body, they carry the risk of toxic side-effects. For example, as discussed in chapter 11, adverse drug reactions are estimated to account for or be associated with 20 per cent of hospital admissions in the elderly. Further, although many physicians rely heavily on prescription drugs to help their patients, it is estimated that 50 per cent of prescriptions are not used by consumers exactly as directed.

<sup>1</sup> Evans, J.R. et al. *Toward a Shared Direction for Health in Ontario*, Report of the Ontario Health Review Panel, Toronto, Ontario, June 1987.

Podborski, S. et al. *Health Promotion Patterns in Ontario*, A Report of the Minister's Advisory Group on Health Promotion, Toronto, Ontario, 1987.

Spasoff, R.A. et al. *Health for All Ontario*, Report of the Panel on Health Goals for Ontario, Toronto, Ontario, August 1987.

<sup>2</sup> Ontario Premier's Council on Health Strategy. *From Vision to Action: Report of the Health Care System Committee*. Ont. Gov't. Toronto, Ontario, May 5, 1989.

It seems important, therefore, to consider alternatives to prescription drugs when the indications for drugs are not specific and when other effective and/or safer treatment methods might help. A detailed examination of alternatives to prescription drugs is outside the mandate of this Inquiry. However, it is important to stress that alternatives do exist and, frequently, are preferable.

For example, some acute and a few chronic conditions benefit from surgical approaches or physiotherapy and other physical treatments. Often attention to psychological and social factors is most important. It is now well recognized that the distinction between the mind and the body is artificial—they are intimately connected and influence each other. Physical well-being is often threatened by emotional conflicts that are not resolved and mental health is threatened by physical illness. Professional psychotherapy, relaxation techniques, planned rest and recreation and spiritual guidance all have their place in helping many people cope with chronic health problems. The beneficial effects of regular physical activity have been demonstrated repeatedly, not only in the promotion of health but also in the management of a number of chronic illnesses. The many links between diet and disease are now frequently emphasized in news media reports and are increasingly recognized by health professionals and the public.

Although, as indicated earlier, this Inquiry was not asked to look at alternatives to prescription drugs, consideration of the subject was inevitable. A number of submissions to the Inquiry called attention to this issue and, of course, there is a large body of professional and lay literature on the dangers of thinking that there is “a pill for every ill.” It is not possible in this report to attempt a systematic examination of alternatives to prescription drugs or to estimate health or economic impacts of promoting their use. However, we believe that a systematic examination,

conducted in accordance with accepted scientific standards, is merited. As an example of areas that deserve more careful examination by both experts and policy makers, a closer look at the role of nutrition in health and illness follows.

The rationale for considering nutrition is the assumption that most nutritional products used in moderation have no harmful side effects; many contribute to improved functioning of the body and not just suppression of symptoms; and most are less costly than prescription drugs. A need exists for a series of studies to determine what funds could be saved by raising awareness among physicians about nutrition and nutritional products and what the benefits of nutritional treatments might be.

One case in point is the management of high cholesterol levels. The prescription drugs for high blood cholesterol are fairly expensive and have known adverse side effects, as well as potential but unknown long-term side effects. The alternative nutritional product, Vitamin B3, or Niacin, costs one-tenth, depending on the preparation. With the new time-release Niacin, the side effects of flushing and transient itchy rash have been practically eliminated although the cost is higher. The cost saving, were physicians persuaded to use Niacin instead of the newer drugs, could be millions of dollars. In the recent well-publicized study on treatment of high cholesterol, released under the auspices of the OMA and the MOH, no mention was made of the cost differential between Niacin and other comparable methods of treatment.

There are two aspects to nutrition. The first concerns **diet** and healthy eating habits; the second is **nutritional pharmacology**, which is the deliberate use of higher than normal amounts of minerals, vitamins, fatty acids, and amino acids as treatments for specific illnesses.



As mentioned, the role of good diet in promoting health and poor diet in raising the risk for some diseases is increasingly recognized. This recognition is yielding interesting information. For example, a study, entitled "Superior nutritional care cuts hospital costs," was published in 1988 by the Nutritional Care Management Institute of Chicago. Pulling together dozens of studies in numerous hospitals with thousands of patients, it concluded that just by improving the intake of calories and protein by hospital patients, the average length of stay can be drastically cut down and the cost per patient can be reduced by 50 per cent.

Bad dietary practice has been incriminated as a cause of a great many illnesses of western man: gastrointestinal diseases, cardiovascular disease and metabolic diseases were all relatively rare prior to the 1900s; diverticulosis and ischemic heart disease were uncommon until after World War II. The U.S. Surgeon General has recently emphasised that we eat too much fat, salt and sugar.

The average diet in North America today contains 18 per cent of calories in refined sugar, a further 18 per cent in refined white flour and another 17 per cent of generally synthetic or refined fats. The immense change in diet over the last 100 years, compared to the previous hundreds of thousands of years, seems to be taking its toll in the form of a wide variety of illnesses. Today's three main chronic diseases—heart disease, cancer and stroke—were much less common 100 years ago. With the huge amounts of money spent on heroic attempts to deal with these illnesses when they become acute, it would seem prudent to redouble attempts at prevention. One way to do this is to expand support for large scale long-term studies on dietary habits and their relation to illness.

In order to deal with the dietary aspects of nutrition, education of consumers, physicians and other health professionals is necessary. If

Ontarians rush to see the doctor or rush to obtain a prescription with every minor complaint, it puts a terrific overload on the health care system. The signposts for future consumer education exist today in the grassroots surge to purchase books on diet and health. Governments are making attempts to bring the food companies into line by requiring proper labelling of ingredients. As yet there are no tough laws dealing with unnecessarily high sugar and fat content in the diet, although it may be that such legislation is coming. In the meantime, vigorous education of the consumer is required so that the consequences of poor dietary habits are understood.

Books are continually being published describing what could be termed "clinical nutritional medicine," in which doctors promote the nutritional approach to combat many chronic, non-life threatening diseases. These nutritional remedies, even though not sponsored by drug companies and medical organizations, are being prescribed, where appropriate, by a growing number of reputable physicians.

This awareness has not been directed top down from the regulatory authorities, the medical journals, the medical associations or the university faculties, but has been stimulated by a bottom up demand from consumers anxious to maintain or regain health without drugs. This grass roots demand is expressed in the growth of the health food chains, the modern preoccupation with diet and exercise, the awareness and interest in acupuncture and herbal medicine, the increased interest in chiropractic, the use of focused nutritional remedies and, in fact, all the realms of holistic and alternative medicine.

Increased public interest in "alternative medicine" is not abating and is a result, to a large extent, of both the failure of traditional medicine to take sufficient interest in and adequately deal with chronic disease and the

continuing education of the populace through the media, bookstores and word of mouth that alternate methods can be helpful.

Advocates of nutritional pharmacology make some important points:

- Despite the recent interest in nutrition there is still widespread ignorance about its relationship to health and illness.
- Traditional western scientific medicine has, until recently, largely ignored this area. Departments of nutritional science are at last gaining higher profile and credibility in medical schools. Nevertheless the education of physicians regarding the diet-illness link remains inadequate; this is even more true with respect to the potential benefits of nutritional pharmacology. A recent comprehensive report "The Impact of Nutrition, Environment and Lifestyle on the Health of Americans" is likely to change this. This 650 page "Kellogg Report," by J.D. Beasley and J.J. Swift, was published in 1989 after seven years of preparation and \$3 million support from the Kellogg and Ford foundations in the U.S.
- There are at least 50 essential nutrients—substances the body must get through the diet. These nutrients are water; carbohydrates for energy; fibre; 10 essential amino acids from which proteins are formed; three essential fatty acids; six major minerals and 15 trace minerals; four fat soluble vitamins and nine water soluble vitamins. Ordinarily these essential nutrients are obtained by a healthy person from an adequate diet. Whereas it is universally accepted that major deficiencies of these nutrients can cause disease (for example, deficiencies of iodine causing hypothyroidism, of ascorbic acid causing scurvy, of thiamine causing beri-beri), it has not yet been widely accepted, or definitively proven, that minor deficiencies of nutrients contribute to many chronic physical and emotional disorders.
- Although recommended dietary allowances—the levels of essential nutrients considered adequate—are valid for the *average* adult, there is a wide biological variation in the need of individuals for specific nutrients. Some persons have higher requirements for certain nutrients and for them an average diet can be inadequate in some respects. This is compounded by the processing and refining of the food products we purchase, which often contain lower concentrations of essential nutrients than the natural products. As a result, many Ontarians may have deficiencies of essential nutrients that go unrecognized yet could reduce their resistance to illness, retard their rehabilitation after other diseases are treated and, in some cases, produce illness directly.
- While anecdotal accounts of successful healing using nutritional treatments abound, there are relatively few large-scale studies of the therapeutic potential of nutrients. Pharmaceutical manufacturers, which do most clinical drug trials, have little incentive to fund such studies although academic centres have shown some interest.

Unfortunately, serious advocates of "alternative" treatments have become associated in the minds of many with anti-establishment, fringe-culture movements. As a result their work is often prematurely dismissed as quackery and not subjected to serious scrutiny and to adequate clinical trials. The neglect of nutritional findings is not new. Although Sir Richard Hawkins wrote about a cure for scurvy "with sower oranges and lemmons" in 1593, his ideas were not embraced by the Royal Navy until 1795—200 years later—and the scientific basis of vitamin C treatment was not established until this century.

If it were possible to treat some disorders with inexpensive nutrients which have few and relatively mild side-effects, rather than expensive and relatively more toxic pharmaceutical products, this would clearly be advantageous. Hippocrates (5th century B.C.) said "Let thy food be thy medicine and thy medicine be thy food" and Maimonides (12th century A.D.) went even further: "No illness which can be treated by diet should be treated by any other means." Although neither of these ancient physicians had available the array of life-preserving pharmaceutical products used by doctors today, the advice quoted would still seem to make sense.

What is more, the savings to our tax-supported drug programs would be considerable if lower cost nutrients were demonstrated to be effective and were prescribed rather than drugs or surgery. To illustrate this point, it is instructive to look at five conditions for which advocates of nutritional pharmacology claim success: benign prostatic hypertrophy, childhood asthma, angina pectoris and related cardiovascular problems, osteoarthritis and elevated cholesterol levels in the blood. Traditional medical and surgical methods are used to treat these conditions but none is entirely satisfactory. If the nutritional treatments that some advocate were as successful or better, very considerable financial savings would ensue, with reduced risk of drug or surgical complications and more opportunities for guided self-medication. Like diabetics who are taught to pay close attention to diet and lifestyle, those suffering from such conditions could be taught to take more responsibility for their own health.

If the advocated nutritional treatments for these five conditions were found to be as effective as traditional treatments and were employed instead of the latter, the theoretical savings can be estimated to be very large indeed. Assuming that nutritional treatments were substituted for all Ontarians suffering

from these five conditions, an estimate of annual savings of up to \$230 million can be made.

It must be stressed that this Inquiry does not have evidence to show that Ontarians being treated for these five conditions can all be safely switched to nutritional treatment. Clearly, steps that must be taken before such changes are implemented require an attitude shift by the professions of medicine and pharmacy and action by government.

Health professionals must turn an open mind to the possibility that minor nutritional deficiencies may cause or contribute to illnesses that are not now regarded as nutritional disorders. (It was only a decade ago that most physicians disregarded the link between diet and certain cancers; now a relationship between excessive intake of fats and inadequate dietary fibre and cancers of the breast and colon is considered likely.) Other conditions, including some viral infections (shingles, infectious hepatitis, etc.) may respond to amino acid and vitamin therapy. Unless the medical profession, and especially clinical scientists, encourage systematic study of nutritional pharmacology, its potential cannot be established.

Governments and their research granting agencies have an important role to play as well. Pharmaceutical manufacturers are not likely to sponsor such research. Drug patents for nutritional products are almost impossible to obtain and the price of these products is one-quarter to one-twentieth of the prescription drugs they might replace. Therefore, pharmaceutical manufacturers would have to be given incentives to produce nutritional products if extensive clinical trials did lead to their widespread use, or alternative production and distribution facilities would have to be organized.



One of the research studies commissioned by the Inquiry, "Citizen Behaviours to Alleviate Minor or Non-Acute Symptoms/Maladies,"<sup>5</sup> examined the question of professional acceptance of non-drug self-care strategies. The study, which consisted of physician and pharmacist interviews, concluded that "...physician and pharmacist education is of primary importance..." if this area is to be supported. "There was unanimous agreement that education is a basic prerequisite to any real change in the system...A number...felt that education must be supplemented by political interventions if a real change in the system is to be felt."

The study came up with a series of recommendations which involve: "1) The development of strategies for educating consumers about effective drug use. 2) Designing consumer education on drug-free self-care behaviours. 3) Exploring innovative approaches to educational strategies, including t.v. and radio, pamphlets and written materials, computers and videos. 4) The establishment of an advisory group on drug-free alternatives. Recommended beginning steps involve educating physicians and pharmacists about drug-free alternatives and deciding on appropriate target groups." Finally, the study made an overall recommendation which suggested "Long-term government support for education on appropriate drug use."

Steps that could be taken include the following:

- A critical review of the extensive but largely anecdotal literature on nutritional pharmacology, sponsored by the MOH. This could be analogous to the review of literature pertaining to the use of prescription drugs (the "Goldberg Report"),

commissioned by the MOH, which sparked the establishment of the Inquiry. A computer data base of publications considered authoritative could be maintained, in collaboration with the Ontario Medical Association, for the use of Ontario's physicians.

- Increased support for departments of nutritional science in Ontario faculties of medicine and joint studies with appropriate clinical departments. These might include clinical trials in which nutritional treatments are compared with traditional medical treatments (drugs, surgery, etc.)
- Organizing a consensus conference of leading clinicians, nutritional scientists and practising physicians experienced in the use of nutritional treatments to explore the state of the art in Canada and, if possible, recommend studies and policy directions.
- Following the literature review and consensus conference, organizing large scale Ontario pilot projects in which promising nutritional treatments are applied. Results would be widely publicized in the professional literature and by professional associations.
- Careful examination of the implications for nutritional treatments of the recommendations of the Health Professions Legislation Review.<sup>4</sup> (Schwartz report)

<sup>5</sup> Hart-Zeldin, Corinne, *Citizen Behaviours to Alleviate Minor or Non Acute Symptoms/Maladies: Final Report to the Pharmaceutical Inquiry of Ontario*.

<sup>4</sup> Schwartz, Alan M. *Striking a New Balance: A Blueprint for the Regulation of Ontario's Health Professions*. Recommendations of the Health Professions Legislation Review, 1989.



## Chapter XI

### Pharmacotherapy for the Elderly

*The solution to the problems of pharmacotherapy as they relate to the elderly in Ontario is just one part of the overall scenario. However, we have elected to cover it in detail because: 1) The elderly, as a group, have a great deal to gain and to lose from pharmacotherapy; 2) Ontario has an increasing number of elderly citizens, especially the “old, old” (over 80); 3) There is widespread concern in this area as evidenced by the many submissions the Inquiry received about the elderly and their drugs; and 4) The details we present relative to the elderly illustrate our approach to pharmacotherapy in general and may reveal some of the concerns addressed in general terms elsewhere in this report.*

#### 11.1 Special Problems of the Elderly

Although it must be kept in mind that not all the elderly need to take medications, many do. The potential for breakdown of organ systems increases steadily with advancing age and more and more pharmacotherapy may be needed as system after system breaks down. This necessarily implies greater potential benefit as well as increased risk of adverse drug reactions and interactions.

The impaired organ systems of the elderly handle drugs more slowly than those of younger people. This can lead to gradual development of toxicity, even though the drug dose remains constant (e.g. the insidious development of digoxin toxicity in a senior whose kidneys are failing). Even slightly impaired thinking can lead to a wide variety of “pill muddles” and result in under- or over-dosage. A senior may properly be seeing several specialists, and it is easy for one physician to prescribe in ignorance of the other’s therapy, which can result in both drug errors and dangerous drug interactions.

However, it is wrong to assume that the only problem is over-treatment of the elderly;

under-treatment is also a common problem (e.g. treatable depression may be thought to be untreatable Alzheimers, heart failure may be under-treated, etc.).

##### 11.1.1 General Principles Underlying the Pharmacotherapy of the Elderly

“The incidence of adverse drug reactions rises with age in the adult, especially after 65 years. The disproportionately large number of drugs that elderly are required to take, poor compliance with dosing regimens and the presence of multiple medical conditions, all contribute to this outcome. In addition, however, medication in this age group carries a risk because the dosing regimens must be modified to suit the characteristics of the elderly body, as is now discussed.

“**Absorption** of drugs may be slightly slower because gastrointestinal blood flow and motility are reduced but the effect is rarely important.

“**Distribution** is influenced by the following changes: body weight is reduced so that

standard doses provide a greater amount of drug per kg; body water is less and water-soluble drugs tend to be present in higher blood concentration (and distribution volume decreased); body fat increases, which tends to lower the blood concentration of lipid-soluble drugs (and increase distribution volume); plasma albumin concentration is reduced giving scope for increased free drug.

**“Metabolism** of some drugs is reduced and hepatic enzyme induction appears to be lessened. Liver blood flow diminishes and drugs that are normally extensively eliminated in first-pass through the liver appear in higher concentration in the plasma (greater systemic availability) and persist in it for longer.

**“Elimination.** Renal blood flow, glomerular filtration and tubular secretion decrease with ageing, a decline that is not signalled by raised serum creatinine concentration because production of this metabolite is diminished by virtue of the relatively low muscle mass in the age group. Indeed, in the elderly, serum creatinine may be within the concentration range for normal young adults even when the creatinine clearance is 50 ml/min (127 ml/min in adult male). Particular risk of adverse effects arises with renally eliminated drugs that have a small therapeutic ratio e.g. aminoglycoside antibiotics, digoxin, procainamide and chlorpropamide. Even drugs that are normally eliminated by metabolism may pose a problem through the accumulation of water-soluble metabolites, which retain pharmacological activity, e.g. hydroxylated metabolites of propranolol and tricyclic antidepressants.

**“Drug Response** may alter with ageing, to produce either a greater or lesser effect than is anticipated in younger adults. Drugs that act on the central nervous system appear to

produce an exaggerated response in relation to that expected from the plasma concentration and sedatives and hypnotics may have a pronounced hangover effect. These drugs are also more likely to depress respiration because vital capacity and maximum breathing capacity are lessened in the elderly. Response to B-adrenoceptor agonists and antagonists diminishes in old age partly, it is believed, through loss of specific receptor-binding sites. Baroreceptor sensitivity is reduced, leading to the potential for orthostatic hypotension with drugs that reduce blood pressure.”<sup>1</sup>

### 11.1.2 Special Product Listing Needs of the Elderly

The Ontario Drug Benefit (ODB) formulary should list an adequate selection of medications to meet the needs of the elderly. Accordingly, the liquid and suppository formulations of important drugs, such as iron or acetaminophen in appropriate concentrations, should be included for those who have difficulty swallowing solids or using solid or standard dosage forms.

**11.1 The Committee therefore recommends that the Drug Quality and Therapeutics Committee be asked to specifically review the availability of liquid and other formulations of drugs such as iron and acetaminophen for those who have difficulty swallowing or using solid dosage forms.**

## 11.2 Drug Utilization, Monitoring and Review

At present, the over-65 population of Ontario represents 11.5<sup>2</sup> per cent of the total and this will increase to 13.5<sup>3</sup> per cent by the year

<sup>1</sup> Laurence, D.R., and P.N. Bennett, *Clinical Pharmacology*, Sixth Edition, Churchill Livingstone, London page 141-142.

<sup>2</sup> Statistics Canada, Postcensal annual estimates of population by marital status, age, sex, and components of growth for Canada and the provinces and territories, Cat. #91-210 1989.

<sup>3</sup> Ministry of Treasury & Economics, Demographic Bulletin: Ontario Population Projections for 2011, Jan. 1989.



2000, with the greatest growth in the over 80 age group. The increasingly aged population in Ontario already utilizes a significant number of prescription and non-prescription medications, and this will increase in the years to come.

By the best present estimate, the over-65 population uses approximately 80 per cent of the ODB budget.<sup>4</sup> While ODB beneficiaries represent 15 to 20 per cent of the population, they consume more than 40 per cent<sup>5</sup> of the prescriptions dispensed in Ontario. This is as a result of a number of factors, including the greater disability and burden of disease experienced by the older population. It is also due to the number of older individuals requiring hospitalization for prolonged periods, or becoming residents in long-term care facilities due to a combination of physical disability and illness, cognitive decline and social isolation.

The present and soon-to-be older generations will, in all likelihood, continue to experience a significant amount of chronic disease that may be relatively and safely ameliorated by rational pharmacotherapy. And this is notwithstanding the research efforts to define risk factors for disease and to determine effective preventative interventions, including social factors that may have an impact on lifestyle practices.

The Inquiry commissioned a research study which was conducted by the department of family and community medicine, University of Toronto and Toronto Hospital: "Prescribing practices in the elderly of a family practice unit...a pilot study"<sup>6</sup> (see appendices, volume II). The following information is derived from that study.

"Eighty per cent of all adverse drug reactions (ADRs) are due to the extension of known pharmacologic properties and are avoidable. The Ontario Medical Association has shown that 33 per cent of all ADRs are in the over 60-year age group, with 20 per cent in the over 70 age group. Of all admissions to hospital due to ADRs, 41 per cent are in the over 60 year age group. The major causes of ADRs are polypharmacy, self medication, lack of compliance, improper storage, physicians' lack of training in geriatric prescribing and poor supervision of elderly patients, dual prescribing systems in hospitals and in general practice, and increased drug sensitivity in the elderly."<sup>7</sup>

The study indicated that multiple drug use in the elderly has many causes, not the least of which are legitimate health needs. But there are also difficulties with respect to physician behaviour: physicians may be unaware of the number of drugs they are prescribing, can make inaccurate diagnoses, take drug histories carelessly, fail to set clear therapeutic goals, have an inadequate knowledge of pharmacotherapy, and have an inadequate medical education related to geriatric pharmacotherapy.

In a review of English-language Canadian literature on prescribing for the elderly, Lexchin states that: "The most apparent conclusion that can be drawn...is that we know astonishingly little about prescribing to the elderly. Only prescribing of benzodiazepines has been examined in any detail...For nearly all other drugs, our knowledge is minimal to nonexistent..."<sup>8</sup>

As part of the ongoing effort to improve the knowledge base of health care professionals and to assess the impact on their prescribing practices, a system of drug utilization review

<sup>4</sup> Based on ODB claims expenditures, 1989-90.

<sup>5</sup> Brief by Greenshield, #105-5200, p.24.

<sup>6</sup> Bloom J.A., M.S. Shafir, J.W. Frank and P. Martiquet, Prescribing Practices in the Elderly of a Family Practice Unit. Final Report to the Pharmaceutical Inquiry of Ontario, December, 1989.

<sup>7</sup> Ibid. Bloom, J.A. p.1.

<sup>8</sup> Lexchin, Joel, "Prescribing for the Elderly: A Review of English Language Canadian Literature," *Canadian Family Physician*, 35:1613-1618 (1989.)

and impact analysis must be developed. This will ensure that the process of improved drug usage is continuously being evaluated and that new findings are integrated into prevailing attitudes and prescribing practices.

This must be coupled with well-developed information systems to help ensure that physicians have available to them current data about medications, as well as individual patient profiles which highlight potential risks for drug-related problems. To this end, record-keeping and the exchange of important disease and medication-related information must be coordinated among prescribers, dispensers and those involved in counselling, monitoring and assuring compliance.

**11.2 The Committee therefore recommends that the smart cards which are to be introduced to facilitate drug utilization, monitoring and review (see recommendation 8.10), be programmed to ensure that problems in pharmacotherapy (e.g. drug interactions) are promptly identified. Electronic communication systems recommended for all pharmacies (see recommendation 8.2) should similarly be programmed to take into account the special problems of prescribing for the elderly. Similar systems should be developed for practising physicians.**

There is also a role for manufacturers in terms of ensuring the safety and effectiveness of new drugs, as these relate to seniors. This point was well made in the submission by the Gerontology Research Council of Ontario (GRCO).<sup>9</sup> GRCO recommended that “Pharmaceutical manufacturers should be encouraged to include seniors in clinical trials of medications, and to test the feasibility of routinely including seniors in all clinical trials. Seniors should be encouraged to co-operate in clinical trials. If this proves

feasible, the Health Protection Branch of Health and Welfare Canada should include as a requirement, mandatory clinical trials with patients in various age groups over age 65.”

**11.3 The Committee therefore recommends that the federal Health Protection Branch and the Ontario DQTC:**

- a) be asked to encourage manufacturers to ensure that, whenever it is relevant and feasible, data from drug trials submitted in support of applications for licensing and listing include data from older individuals so that safety and effectiveness in that population can be assessed. Similarly, Ontario faculties of medicine sponsoring drug trials should be asked to include older subjects whenever this is relevant or feasible; and
- b) be asked to require pharmaceutical manufacturers to provide specific data and recommendations for prescribing for older patients, where this is relevant.

The general principles governing pharmacotherapy for the elderly have been converted to the following 10 “Rules for Prescribing for the Elderly” which were published in the World Health Organization report:

- “1) Think about the necessity for drugs. Is the diagnosis correct and complete? Is the drug really necessary? Is there a better alternative?
- “2) Do not prescribe drugs that are not useful. Think carefully before giving an old person a drug that may have major side effects, and consider alternatives.
- “3) Think about the dose. Is it appropriate to possible alterations in the patient’s physiological state? Is it appropriate to the patient’s renal and hepatic function at the time?

<sup>9</sup> Brief #66-3100.

“4) Think about drug formulation. Is a tablet the most appropriate form of drug or would an injection, a suppository or a syrup be better? Is the drug suitably packaged for the elderly patient, bearing in mind his disabilities?

“5) Assume any new symptoms may be due to drug side effects or, more rarely, to drug withdrawal. Rarely (if ever) treat a side effect of one drug with another.

“6) Take a careful drug history. Bear in mind the possibility of interaction with substances the patient may be taking without your knowledge, such as herbal or other non-prescribed remedies, old drugs taken from the medicine cabinet, or drugs obtained from friends.

“7) Use fixed combinations of drugs only when they are logical and well studied and they either aid compliance or improve tolerance or efficacy. Few fixed combinations meet this standard.

“8) When adding a new drug to the therapeutic regimen, see whether another can be withdrawn.

“9) Attempt to check whether the patient’s compliance is adequate, e.g. by counting remaining tablets. Has the patient (or his relatives) been properly instructed?

“10) Remember that stopping a drug is as important as starting it.”<sup>10</sup>

The issue of optimal pharmacotherapy for the elderly is being addressed in many jurisdictions.<sup>11</sup> A leading article in England<sup>12</sup> asked the question: “Need we poison the elderly so often?” The article suggests that the myth of “a pill for every ill” may be becoming displaced by a different myth: “an ill for every pill.” Clearly, perspective is required.

There is a relative lack of information about geriatric drug therapy and what is known is *not* readily available to physicians at the time they are prescribing for elderly patients. As people age, they are at increasing risk of developing a growing number of diseases, especially those of a chronic nature. Some of these diseases will affect the response to drugs. At the same time, they are more likely to benefit from drug therapy and to be prescribed more medications, or to self-medicate to gain symptomatic relief. Finally, they are more likely to see multiple specialists to deal with multiple problems. Any of these physicians may order drugs without knowledge of the medications that other physicians have prescribed. Accordingly, there is a need for coordination of geriatric drug therapy and the patient’s general or family physician is usually particularly well suited for this role. However, because a large knowledge base that is kept up to date is implied in the role, there may be practical difficulties for a general practitioner, including a less than optimal education about pharmacotherapy in the elderly and a poor information base, especially for drugs prescribed by other physicians.

It is easy to recommend that all patients have a personal physician. It is more difficult to ensure this in an age of mobile populations, although the elderly probably move less than the physicians caring for them. Physician shortages are local and regional rather than general. Specialists and special clinics often provide excellent care, but communication skills may lag behind clinical expertise. It is commonplace for a family physician to receive a hospital discharge letter months after the patient has been discharged. This becomes a much less serious problem if the institution has proper discharge procedures (see recommendation 8.17) which help ensure continuation of optimal therapy.

<sup>10</sup> In Caird F.I. (ed) *Drugs for the Elderly*. Copenhagen: World Health Organization, 1985.

<sup>11</sup> Cartwright, Ann and Christopher Smith, *Elderly People, their Medicines, and their Doctors*, Rutledge; New York, 1988.

<sup>12</sup> “Need we Poison the Elderly so Often?” *The Lancet*, July 2, 1988.



As the elderly are especially prone to multiple illnesses, they are particularly liable to suffer adverse drug reactions due to drug and illness interactions. This is especially so if the multiple prescribers do not know the other drugs the patient is taking. Such patients benefit immensely (as does the system) if they carry an up to date medication list and choose to use a single pharmacy. Clearly the drug list is only useful if it is used and general practitioners and pharmacists need to share the information with those who need to know it, especially nurses and other health care providers caring for the patient.

Keeping the drug list up to date is one of the reasons experienced physicians recommend that patients on complicated medication regimens bring all medications at each visit to a doctor or hospital. This also permits: 1) an improved opportunity to check compliance; 2) the opportunity to reinforce simple education (e.g. "this pill is for your heart;") 3) the opportunity to confiscate obsolete medication and minimize "pill muddle;" 4) the opportunity to minimize errors because, despite everyone's best intentions, medication lists may not always be up to date (changes are made by phone when test results become known, etc.); and 5) a reduction of potential errors when medications are moved out of the container in which they were dispensed.

**11.4 The Committee therefore recommends that:**

- a) The Ministry of Health, with the advice of seniors' organizations, develop guidelines and an information campaign aimed at ensuring that by 1994, all patients, especially the elderly, choose and remain with one personal physician.**
- b) The Ontario Medical Association, the Ontario Hospital Association and the College of Physicians and Surgeons of**

**Ontario establish guidelines by 1992 to ensure that specialist physicians and hospital clinics meticulously and expeditiously inform a patient's family physician of suggested alterations in the patient's drug regimen.**

- c) The College of Physicians and Surgeons of Ontario, the College of Family Practice, and the Ontario Medical Association establish guidelines, by 1992, to ensure that primary care physicians maintain and regularly update the older patients' medication list. This information should be shared with other professionals caring for the patient.**
- d) The Ontario Medical Association and the Ontario Hospital Association, in conjunction with seniors' organizations, establish guidelines by 1991 to communicate to physicians the need to require patients on complicated drug regimens to bring all medications to each visit to any doctor or hospital.**

### **11.2.1 Prescription Drug Addiction and the Elderly**

It is very easy for prescribers to start hypnotic, sedative and tranquillizing drugs but it may be very hard for patients to stop them. Distressing confusional states, depression and falls are all too often the result. Psychological and sometimes physical dependence occurs all too often. Clearly prevention is better than treatment. A simple and effective way of dealing with this problem was presented to us. The approach is positive and non-judgemental and involves requesting consultations from appropriate experts prior to renewing sedatives for long term use.<sup>15</sup>

**11.5 The Committee therefore recommends that, by 1992, the College of Physicians and Surgeons of Ontario, the Royal College of**

<sup>15</sup> Dr. H. Cohen—in his presentation as part of the Council on Aging of Ottawa-Carleton, brief #118-5100.

**Dental Surgeons and the Ontario Medical Association develop guidelines in order that prescriptions for hypnotics, sedatives and tranquilizers be issued for the shortest possible time and be clearly marked “no repeats” unless there is a clinical indication to the contrary.**

Despite this recommendation, we recognize that in some cases, patients with severe, long-term anxiety states may require long-term use of anxiolytic drugs.

The Committee also suggests that persons habituated to hypnotics, sedatives and tranquilizers are helped to withdraw from the regular use of these drugs. (See recommendation 9.6.)

We wish to emphasize that optimal rational pharmacotherapy for the elderly may well imply the decision not to use certain prescription or over-the-counter medications. Proper diet, proper use of simple physical and household remedies, and an appropriate attitude to self limiting aches, pains, and illness are essential. (See also chapter 10)

We believe that rational pharmacotherapy can and should play an important role in securing the best possible quality and length of life for elderly Ontarians.

### **11.3 Education of Physicians and Other Health Care Providers**

The goal of the health care professions should be to ensure that older individuals have the medications they require, in the appropriate dosages and for the necessary duration of therapy. This requires that physicians have a competent command of the factors that

impact on drug pharmacokinetics, pharmacodynamics and other effects, as well as those factors that ensure appropriate drug utilization and compliance. It requires the same from pharmacists and other health care providers who participate in the chain of events that affects medication use by the older person.

This was recognized by the North York Inter-Agency and Community Council<sup>14</sup> which recommended that the education of physicians and pharmacists should specifically include knowledge about the geriatric population and medication, how the ageing organs deal with medication and how medications interact in the aged person.

Until recently, physician training focused only minimally on the geriatric population. Despite the fact that, with the exception of obstetricians and pediatricians, most physicians will spend a considerable amount of clinical time caring for older patients, there is little in the core curriculum of medical schools pertaining to the older population. A few lectures, occasional clinic groups, and some available selective and elective courses have provided all the potential exposure that medical and other health care students have of the older population. Just the fact that many of the courses are elective suggests to medical students that caring for the elderly is an optional, rather than an intrinsic, part of medical education and responsibility.

Concern in this regard was reflected in a number of submissions, including that of the Ontario Coalition of Senior Citizens' Organizations<sup>15</sup> which proposed that every medical school should provide special education in geriatric pharmacology in order to improve health care for the elderly. The Manitoulin-Sudbury District Health Council<sup>16</sup>

<sup>14</sup> Brief #104-5100.

<sup>15</sup> Brief #76-5100.

<sup>16</sup> Brief #137-5400.

called for both significant curriculum increases in geriatrics and mandatory continuing education programs in the area of geriatrics and geriatric pharmacology.

Recent attempts to rectify the situation by the development of more formalized departments and divisions of geriatrics have yet to be reflected in the knowledge base of, and attitude towards, medical care and drug usage in the older age group.

In order to rectify that situation, it will be necessary to implement changes to both undergraduate and postgraduate education programs.

**11.6 The Committee therefore recommends that all Ontario faculties of medicine be requested to review their undergraduate and postgraduate curricula, by July 1, 1992, to ensure that:**

- a) appropriate instruction and experience are provided in prescribing for the elderly, emphasizing the differences from prescribing for younger patients; and
- b) all family medicine and specialty post-graduate training programs have specific rotations in geriatric medicine, as appropriate, including supervised pharmacotherapy experience in ambulatory and long-term, as well as acute care settings.

Continuing medical education programs must also be amended to bring about modifications in attitudes in order to eliminate the extremes of therapeutic nihilism and irrational polypharmacy.

**11.7 The Committee therefore recommends that the Ontario Medical Association be asked to review, by January 1, 1992, the adequacy of continuing medical education courses available to Ontario physicians with respect to all aspects of geriatric medicine**

**and pharmacotherapy for the elderly. The OMA, in collaboration with the Ontario faculties of medicine, should be asked to ensure that educational gaps are filled so that Ontario physicians can readily and regularly update their knowledge and skills with respect to caring for and properly prescribing for the elderly.**

**11.8 The Committee also recommends that the Royal College of Physicians and Surgeons and the College of Family Practice of Canada be requested to review their educational objectives and requirements with regard to geriatric medical education and pharmacotherapy for the elderly.**

#### **11.4 Hospitalization/Institutionalization of the Elderly**

A substantial portion of Ontario drug costs are spent on behalf of individuals who are institutionalized in acute care hospitals and long-term care facilities such as nursing homes, homes for the aged and chronic care hospitals. The reasons for admission to these institutions differ; length of stay depends on the reason for admission and the type of institution. The pattern of drug prescribing and usage depends on the nature and duration of the medical condition(s) that require therapy.

Older individuals are admitted to acute care hospitals from their homes, or from long-term care facilities unable to provide the acute care required during medical crises. The majority of older individuals are able to return home, or to the institution from which they were transferred, following treatment. Some, however, cannot be readily discharged and occupy a bed within the acute care facility while waiting for placement in a suitable long-term care facility. Many general hospitals in Ontario have populations in which more than



50 per cent of patients are over 65 years of age while 20 to 25 per cent are over 75 years old. The number of patients “awaiting placement” at any given time at acute general hospitals may range from 20 per cent to 40 per cent of the potential medical patient population.

The majority of older patients are admitted to general hospitals for acute inter-current medical problems for which medical intervention represents a potential benefit. Those admitted from their own homes have the greatest chance of being discharged back to their homes. For those admitted from long-term care institutions, arrangements for discharge back to the institution are often made early after admission. However, as a group, older individuals risk not being able to be discharged back into the community, or to the level of care provided by a nursing home/home for the aged, as a result of a complexity of medical problems that undermine their ability to function.

In addition to the complex medical problems that often undermine the older patient’s ability to function optimally, drug therapy may aggravate impaired physical and/or mental functions. Hospitalized elderly patients are at risk due to multiple drug prescribing (polypharmacy), drug interactions and adverse drug reactions. The latter category includes outcomes from various aspects of drug prescribing (under-prescribing, over-prescribing, inappropriate drug dosages, etc.) and is one of the causes for admission to hospital for a significant proportion of older patients.

There is evidence to suggest that methods to improve the knowledge base for drug prescribing in the elderly, as well as an enhanced level of geriatric care education (through geriatric consulting teams, geriatric units, etc.)

exist and, when implemented, may reduce the degree of inappropriate drug utilization in this group.

A number of steps can be taken by general hospitals to decrease the likelihood of inappropriate drug prescribing for, and utilization by, older patients. These include:

- A hospital drug formulary that clearly lists the drugs available within the hospital and contains the appropriate range of dosages for older patients, together with some basic drug prescribing information that is readily available to all members of the health care team.
- On-site interaction/consultation among members of the department of pharmacy, physicians and nurses to evaluate and review medication use by older hospitalized patients. (The Ontario Coalition of Senior Citizens’ Organizations<sup>17</sup> has recommended in this regard that a geriatrician be hired to consult with the pharmacy medical advisory board of each acute care hospital over 300 beds, and every long-term care institution, and to assist with peer review of elderly patients’ drug treatments, especially in nursing homes.)
- The development of geriatric consultation teams, which utilize the expertise of geriatricians (or physicians especially interested in the care of the elderly), and clinical nurse specialists in geriatrics, who can participate in the evaluation and review of drug usage.
- A drug utilization review process for the hospital that focuses on specific high risk drugs (psychotropic, cardiac, anti-inflammatory drugs, etc.) and that can evaluate drug usage in general, as well as specifically identify physicians who might benefit from special educational upgrading.

<sup>17</sup> Brief #76-3100.

- Periodic educational activities directed to the medical and nursing staff to upgrade generally the knowledge of drug prescribing for the older patient.
- Improved education of the elderly\_\_on the expected outcome of the drug therapy, possible side effects, and administration directions—is desirable and could improve compliance. Methods could include verbal interaction, written reinforcement and self administration of drugs prior to discharge to assess the effectiveness of the education and determine the expected level of compliance.

The adoption of certain procedures in the areas of acquisition, distribution, prescribing and dispensing would improve pharmacy systems and routines in acute care hospitals. Specific recommendations and further discussions on these topics are found in other areas of the report. (See section 5.2 for a discussion of hospital drug acquisition; section 6.3 with respect to unit dose; chapter 9 with respect to drug utilization review; and chapter 6 with respect to maintenance of patient profiles in pharmacy practice.)

**11.9 The Committee therefore recommends that the Ministry of Health, in conjunction with the Ontario Hospital Association, the Ontario Association of Non Profit Homes and Services for Seniors and the Ontario Nursing Home Association require that, by July 1, 1992, all acute care hospitals and geriatric long-term care facilities establish appropriate systems to monitor the pharmacotherapy of elderly patients.**



## Chapter XII

### Conclusions and Recommendations

*The preceding chapters have presented the findings of the Pharmaceutical Inquiry of Ontario. These are now summarized, our recommendations are listed and an estimate of the resultant costs and savings is offered.*

#### 12.1 Issues Raised by the Committee

Since our purpose has been to recommend improvements to the use of prescription drugs in Ontario, the focus has been on problems and inadequacies. However, it is important to place these in the appropriate context. It is our conclusion that Ontarians generally do receive excellent treatment involving prescription drugs. For the most part, pharmaceutical products are safe and effective and appropriately prescribed, dispensed and used. Prescription drugs are generally available promptly. They are affordable for most Ontario residents. Since prescription drugs are an important component of modern health care, the Committee found all this reassuring.

Nevertheless problems were identified. For example:

- Some pharmaceutical products listed in the Ontario Drug Benefit plan formulary (the costs of which are reimbursed with public funds) are sub-optimally effective and/or have unfavourable benefit/risk ratios.
- Some physicians do not prescribe drugs effectively or efficiently; misprescribing is especially problematic in the case of the elderly. A particular concern is that some physicians prescribe powerful drugs when other therapeutic approaches may be safer or more effective. Some physicians inappropriately prescribe expensive, newly-released products before trying less costly and well-established drugs.
- Physicians are not as well prepared for prescribing the thousands of drug products available as they might be, especially with respect to the elderly. The continuing education of physicians with respect to the use of new drug products requires improvement.
- Pharmacists are not meeting their full professional potential as members of the health care team. They do not have the opportunity to use all the skills and knowledge they have acquired because their role is defined too narrowly.
- Some Ontarians who need prescription drugs do not have ready access; they do not qualify for government programs because they are under 65 and are not receiving social assistance and they cannot purchase adequate private insurance. The two groups most at risk are those who do not have insurance through the workplace but have low incomes (the "working poor") and people with extraordinary drug costs due to severe chronic disease or disability. Between 600,000 and 700,000 individuals fall into one of these groups and do not have adequate access to needed drugs.



- The public expects Canadian governments to assume major responsibility in the prescription drug field; specifically, governments must ensure that drugs are safe, effective and affordable. Yet coordination among federal and provincial ministries is less than optimal. There is no national policy regarding drug interchangeability and the process of approval and licensing of drugs is more complicated and time consuming than it needs to be.
- Although provincial government policies have encouraged generic drug product use, prescription drug costs have not been well contained.

The large number of recommendations offered in the report (147) is a reflection of the complexity of the prescription drug field and the broad mandate of the Committee. The recommendations have been introduced in the appropriate context within the chapters which contain the underlying rationale; they are repeated at the end of this chapter so that the complete picture can be seen more easily. The thrust of the major recommendations is outlined as follows:

Recommendations intended to produce improvement in the **quality** of treatment involving prescription drugs include those that will:

- enhance the prescribing skills of Ontario physicians through better education, drug utilization review and better post-marketing surveillance of drug products;
- promote greater use of the knowledge and skills of pharmacists, improve their education and define the role of auxiliary personnel;
- improve the packaging, labelling and dispensing of prescription drugs, in both health care institutions and community pharmacies;

- produce a restructured, more restricted ODB formulary;
- protect the viability of the wholesale distribution industry in Ontario and introduce performance standards;
- promote the development of modern information systems; and
- expand and improve consumer education.

Recommendations designed to improve access to needed drug treatment for all Ontarians include those that will:

- extend government drug benefits to high risk groups (persons suffering from certain chronic illnesses or faced with sudden catastrophic drug costs); and
- extend government drug benefits to the “working poor.”

Recommendations intended to control the cost to the taxpayer of prescription drug programs include those that will:

- eliminate “special authorizations” of drug products not listed in the ODB formulary;
- roll back some prescription drug prices and contain future price increases;
- limit the formulary entry price of generic drugs;
- restructure the ODB formulary so that it will contain drugs with more favourable benefit-risk and benefit-cost ratios;
- eliminate the 10 per cent surcharge payable to pharmacists on direct purchases from manufacturers;
- accelerate and simplify the approval of new drug products; and
- institute a prescription co-payment for those persons now eligible for government drug benefits who are not receiving social assistance, to a maximum of \$250 per person in any year.

## 12.2 Estimating the Costs and Savings of the Recommendations of the Inquiry

The Pharmaceutical Inquiry of Ontario has attempted to estimate the cost implications of its recommendations. The 1988-89 fiscal year is the last year for which we have complete information on the costs of the ODB program, and is taken as the reference point. The calculations which follow indicate what the costs of the ODB would have been had the recommendations in the report been in force for that fiscal year.

There are recommendations that relate directly to the cost of operation of the ODB, and we were able to derive reasonable estimates for them. Other recommendations are more global and refer to changes in the education and training of professionals, rational prescribing and dispensing, linking data and monitoring use, and the role of pharmaceutical products in health care. These call for more fundamental changes in health care in Ontario, and we have no real way for estimating economic impact, either in terms of costs or benefits that would accrue from improved health care.

### 12.2.1 Expenditures of the Ontario Drug Benefit Plan

During the 1988-89 fiscal year, the ODB program paid \$629.9 million in benefits for 1.5 million recipients to cover the costs outlined in the table below:

### Expenditures and Claims Ontario Drug Benefit Program 1988-89

Expenditures	Amount	Claims
Prescription Drug Costs	\$354,884,500	32,022,900
Upcharge or Surcharge	35,488,400	
Dispensing Fees	188,803,200	
Non-Prescription Drug Costs	50,774,300	3,348,600
<b>Totals</b>	<b>\$629,950,400</b>	<b>35,371,500</b>

Drug manufacturers were paid \$405.7 million for drug products. The surcharge or upcharge was paid to the pharmacists. About half of the drugs were sold to the pharmacists directly; they retained the associated upcharges (\$17,744,000) as a part of their gross income. For the drugs sold indirectly, it is estimated that the pharmacists paid wholesalers about \$14,195,400 in fees and retained \$3,548,800. The gross income of pharmacists in fees and upcharges was about \$210.1 million, or about one-third of the total ODB costs.

### 12.2.2 Estimating the Impact of the Recommendations on the Costs of the Ontario Drug Benefit Program

**12.2.2.1 Elimination of Special Authorizations:** Special authorization (SAs) expenditures were reduced in mid-1989 as a result of an interim recommendation by this Inquiry. Had SAs been permitted to continue, the estimated costs for 1988-89 would have been about \$22 million. By 1988-89, SA costs had reduced to \$13.2 million for the year. Had the SAs been completely phased out, a conservative estimate is that the ODB costs would have been reduced by two-thirds to \$7.3 million for the 1988-89 fiscal year.

The estimated saving due to this recommendation is \$14.7 million.

#### 12.2.2.2 Constraining the Price of

**Prescribed Drugs:** In section 5.4 of the report, we recommend that the prices be rolled back to the 1986 formulary levels and then be allowed to increase at the rate of increase in the consumer price index. In recommendation 5.2, we also suggest that the price of generic drugs be set at 60 per cent of the reference price for the patented medicine. We estimate that had the recommendation been implemented, there would have been a 5 to 10 per cent decrease in the cost of prescribed drugs. The estimated savings due to these recommendations range from \$17.7 million in drug costs and \$1.8 in surcharge costs to \$35.9 million in drug costs and \$3.5 million in surcharges.

The mid-range estimate of the savings is \$29.5 million.

**12.2.2.3 Distribution Costs:** In chapter 6 of the report, the Inquiry recommended that the surcharge or upcharge for drugs sold directly be dropped and that pharmacists receive 8 per cent of the drug costs for drugs purchased through wholesalers. Approximately half of the prescribed drugs are sold directly by the manufacturer to the pharmacists. The recommendation would reduce the upcharge or surcharge costs (\$39.49 million) by 60 per cent to \$14.2 million.

The estimated savings of the recommendation is \$21.3 million.

**12.2.2.4 Prescription Renewals:** In chapter 7, the Inquiry recommended that the professions of pharmacy and medicine jointly study the appropriateness of the quantity of drugs on a prescription and issue appropriate guidelines. It is difficult to predict the outcome of these discussions and the effects, on quantities prescribed, of any guidelines that might be developed. We do have some estimates based on a study done for the Inquiry by Dr. Paul Gorecki (see appendices, volume II.) Dr. Gorecki compared the frequency with which 40 drugs used for chronic conditions were renewed in British Columbia and Ontario.

These drugs in Ontario accounted for about one-third of all ODB claims for the month of March in 1986. He estimated that a 20 per cent reduction in claims could be achieved if the Ontario guidelines resulted in an increase in prescribing quantities to the maximum of 250 days for all maintenance drugs, as is the case in B.C. Not all claims are for repeat prescriptions nor is it reasonable to assume that a 250-day limit is appropriate for all repeat prescriptions. We estimate the potential reduction in the number of claims to be in the order of 10 per cent. There should be no drop in the costs of drugs; the resulting savings would come from the reduced number of dispensing fees. Using the 10 per cent estimate, the potential for savings is \$18.9 million.

**12.2.2.5 Add Low Income and Disabled Persons to ODB:** In chapter 9 of the report, the Inquiry recommended that elderly recipients of ODB who do not receive the social assistance supplement (GAINS) be required to make a copayment of not more than \$4 a prescription. A cap of \$250 was also recommended as the limit that any one person would pay per year. We estimated that the average annual cost for a senior citizen making co-payments would be between \$65 and \$90. The estimated savings for the ODB were between \$81.6 million and \$140.8 million, depending on the amount of the copayment and the degree to which drug use would decline.

The mid-range estimate of the savings for ODB was \$111.2 million.

The Inquiry recommended that ODB benefits be extended to low income and disabled persons with high drug costs who were not eligible for ODB benefits. The estimated costs for extending the benefits ranged from \$59.2 million to \$232.5 million.

The mid-range estimate of the **added cost to ODB** was \$150 million.



The Inquiry further recommended that the co-payment be introduced for low income and disabled individuals who do not received social assistance. This would reduce the mid-range **added cost to ODB** from \$150 million to \$95 million.

The costs and savings of the recommendations dealing with the Ontario Drug Benefit plan are summarized in the following table. The values inserted into the table are the mid-range estimates for the various recommendations. The totals suggest that the recommendations would add about \$95 million and save \$195.5 million, resulting in a net savings of about \$100 million a year. This is approximately equivalent to a 15 per cent reduction in the annual costs of the ODB program.

**Savings and Costs of Recommendations  
Regarding the Ontario Drug Benefit  
Program 1988-89**

Recommendations	Added Savings (millions)	Cost
Eliminate Special Authorizations	\$14.7	
Constrain Price Increases for Prescribed Drugs	29.5	
Modify Distribution Costs	21.3	
250 Day Supply Limit for Prescription Renewals	18.8	
Copayments for Elderly Not Receiving Social Assistance	111.2	
Extend ODB Coverage with Copayment to Low Income and Disabled Persons		\$95.0
<b>Totals</b>	<b>\$195.5</b>	<b>\$95.0</b>

### 12.2.3 Economic Impact of Other Recommendations

The Inquiry recommended that the scope of the Drug Quality and Therapeutics Committee (DQTC) be expanded to include a complete review of all drug products

currently listed in the formulary, by defining the limited use of selected drug products, and by including assessments of the marginal costs and effectiveness of new drug products in its reviews. The expanded activities would probably double the annual operating costs of the DQTC from \$170,000 to \$340,000.

The creation of a doctorate in pharmacy program is estimated to cost about \$950,000 a year. Present plans calls for the costs of the program to be shared by the University of Toronto and the participating teaching hospitals, and for a reallocation of existing funds to meet the costs.

It would take about \$3 million to operate a second faculty of pharmacy. The start-up costs and capital expenditures would depend on the resources available at the university where the faculty would be located.

The introduction of a clinical preceptor year to a pharmacy program is estimated to cost about \$1.2 million in operating costs a year.

The total of these identified cost increases is \$5.32 million.

There are recommendations for which no cost estimates are available. These include the development of drug profiles for patients in the pharmacy, linkage between hospital and community pharmacies, reimbursement schedules for the expanded activities of pharmacists in the community, monitoring of drug compliance, or the cost of publishing "Medications of Choice." In chapter 10, alternatives to medications for managing chronic illnesses and problems are presented. In reality we do not know the extent to which pharmaceutical products could be replaced with other forms of management, or what the net costs would be for the health care sector. It is reasonably clear that the potential costs and savings of rational health care would be of greater importance, if realized, than the specific recommendations regarding the operation of the ODB program per se.

## 12.3 Conclusion

We are convinced that the changes recommended in this report will improve a system that is already very good. Many of these changes will require the expenditure of more public funds. However, in today's economic climate it is not realistic to recommend new expenditures, however justified, unless off-setting savings can also be identified; this we have attempted to do. The net effect of our recommendations would actually reduce the cost of taxpayer-supported drug programs in Ontario while, we believe, improving the quality of prescription drug use and access to needed drug products to all Ontarians.

In order for this to be achieved some trade-offs are necessary. They will require contributions from several important interest groups, in the form of somewhat lower profits for some pharmaceutical manufacturers and pharmacies and a co-payment (up to an acceptable annual maximum) for ODB-eligible persons not receiving social assistance.

We are convinced that if implemented, the recommendations that follow will serve the public interest and, in the long run, the interest of health professionals, manufacturers and distributors of prescription drugs.

## 12.4 Summary of Recommendations

The recommendations contained in the report are listed by chapter as follows. It should be noted that not all chapters contain recommendations.

### Chapter IV The Formulary and the DQTC

**4.1** The Committee therefore recommends that an Ontario Drug Benefit formulary be retained but with significant changes.

**4.2** The Committee therefore recommends that after publishing the January, 1991 edition, the formulary be frozen in order to permit a new unencumbered formulary to be created. The benefits listed in the January, 1991 edition would therefore only continue until the publication of the unencumbered formulary, at which time all existing benefits would be terminated in favour of the new formulary benefits.

**4.3** The Committee therefore recommends that, beginning immediately, a review with respect to efficacy, safety, equivalence and cost of all products now listed in the formulary be initiated by the Drug Quality and Therapeutics Committee.

**4.4** The Committee therefore recommends that mechanisms be developed to permit a drug product to be listed at the recommendation of the DQTC, even when no submission was initially made by a manufacturer.

**4.5** The Committee also recommends that provisions be made to allow the formulary to take on a dynamic character; single and multiple source products should be regularly re-evaluated and then be retained, deleted or redefined by category.

**4.6** The Committee therefore recommends that the Ministry of Health, in cooperation with the College of Physicians and Surgeons of Ontario, the Royal College of Dental Surgeons, the Ontario Medical Association, the Ontario College of Pharmacists, and the Ontario Pharmacists' Association launch a program by January 1, 1992, that will monitor drug use and increase prescribers' accountability for their pharmacotherapy.

**4.7** The Committee therefore recommends that the development and use of multi-source products in non-conventional dosage forms be promoted where possible by assembling and promulgating criteria which permit interchangeable products of non-

conventional dosage or administration forms to be identified and listed.

4.8 The Committee therefore recommends that the Ministry of Health, the College of Physicians and Surgeons of Ontario, the Royal College of Dental Surgeons, the Ontario Medical Association and the Council of Faculties of Medicine work together to develop mechanisms to promote generic prescribing when this is appropriate.

4.9 The Committee therefore recommends that, after the January, 1991 edition, the Ministry discontinue the present system of formulary publication wherein bi-annual deadlines are specified and devise, in its place, a continuous system of product review.

4.10 The Committee therefore recommends that an expert drug advisory committee, as represented by the present DQTC, be retained, with terms of reference similar to those already established, but modified as proposed in recommendation 4.11.

4.11 The Committee therefore recommends that the DQTC's terms of reference be reviewed by January 1, 1991 and consideration be given to:

- a) An expanded mandate that authorizes more effective evaluation of drug product cost factors; and
- b) An expanded mandate, along with appropriate resources, that will permit the monitoring of the impact of formulary changes.

4.12 The Committee therefore recommends that the Ministry and the DQTC become more active in regularly communicating with health care professionals about formulary benefits and the review process.

4.13 That the special authorization program be discontinued in its present form.

4.14 That all drug products to be authorized for payment under the Ontario Drug Benefit program be approved by the DQTC. (See recommendation 4.20 for the transition period.)

4.15 That all drug products authorized for payment by the Ministry of Health be listed in the formulary with specifications of the conditions, if any, under which they are eligible for coverage under the Ontario Drug Benefit plan.

4.16 That all drug products for which special authorization issuances have been granted be reviewed comprehensively by the DQTC. We further recommend that this be done in order of their frequency of use (commencing with the most commonly used), using the criteria required for formulary listing. All drugs approved by the DQTC after review should be listed in the formulary. Those drugs that fail to gain approval by the DQTC should neither be listed in the formulary nor be eligible for payment by the Ministry of Health.

4.17 That the formulary contain two categories of drugs: *regular use* and *limited use*. The cost of regular use drugs should be reimbursed whenever they are prescribed and dispensed to persons eligible for Ontario Drug Benefit programs.

*Limited use* status may be granted to other drug products that will only be reimbursed under conditions determined by the DQTC and set forth in the Ontario Drug Benefit formulary. For example, *limited use* status may be granted when one or more of the following conditions apply:

- a) when the limited therapeutic conditions that were determined by the DQTC and set forth in the Ontario Drug Benefit formulary have been met;



- b) when *regular use* drugs have been tried and found ineffective, or have caused an adverse effect for a particular patient; and
- c) when alternative *regular use* drugs are contraindicated, due to concomitant therapy or to particular patient characteristics.

It would be the professional responsibility of the prescriber to verify that the condition(s) have been met.

4.18 That the conditions and restricted indications, if any, under which drugs will be authorized for reimbursement be clearly indicated. This may be done through appropriate footnotes or other means in the formulary.

4.19 That all drug products for which past special authorization issuances have been granted, once they are reviewed by the DQTC, be caused to fall into only one of the following categories:

- a) Formulary listing with *regular use* status;
- b) Formulary listing with *limited use* status; and
- c) Ineligibility for reimbursement by the government of Ontario.

4.20 That during the transition period, until the DQTC is able to review drugs for which special authorization issuances have been granted, all current special authorization drugs awaiting review be permitted to maintain their special authorization status. However, there should be a strict moratorium on the addition of any new products to special authorization status.

4.21 That the DQTC establish a mechanism to expeditiously review new drugs which are major therapeutic advances.

4.22 The Committee therefore recommends that while the present Ontario policy of drug interchangeability, which promotes generic drug substitution and price competition, should be continued:

- a) The Ontario College of Pharmacists direct pharmacists to refill prescriptions with the same product as originally dispensed when its price is equivalent to competing products. (It is understood that when there is a substantial price difference, pharmacists will dispense the drug product priced at the level at which they will receive reimbursement.)
- b) "No-substitution" prescriptions no longer be included as benefits under the ODB plan; where the patient requests that the specific product prescribed be dispensed, the patient should pay for the difference in price above the lowest cost product for which the pharmacist will be reimbursed.
- c) The Ministry of Health, on the advice of the DQTC, establish a mechanism whereby a physician can request that a specific product be permitted as a benefit (the cost of which would be fully reimbursable to the pharmacist) for those very rare situations where a particular patient cannot tolerate or benefit from the lowest priced product.
- d) Policy and, if necessary, legislation be altered to require pharmacists to inform both patients and prescribers that product substitution has occurred.
- e) When a new generic preparation first comes into general use, the Ministry of Health require the generic manufacturer to publicize appropriate information to prescribers, as innovative manufacturers now do.

4.23 The Committee therefore recommends that the DQTC be empowered to review applications and make recommendations to

the Minister of Health with respect to the interchangeability of drug products independent of the status of the products as benefits under the Ontario Drug Benefit program. If it is deemed necessary to change the legislation or regulations to make this possible, the appropriate change should be initiated.

## Chapter V Acquisition of Drugs

5.1 The Committee therefore recommends that the government of Ontario take the lead in promoting federal-provincial and interprovincial agreement for a Canada-wide interchangeability policy. Health and Welfare Canada should be given a wider mandate: in addition to confirming the safety and efficacy of drug products, the approval process should also include a determination of whether the product is bioequivalent to, and interchangeable with, other approved products.

5.2 The Committee therefore recommends that a generic equivalent of a brand-name product not be listed in the formulary for the first time at a price which exceeds 60 per cent of the reference price of the equivalent brand-name product. That reference price will be the listed price of the brand-name product found in the formulary immediately prior to the one in which the generic product is to first appear.

5.3 The Committee therefore recommends that all prescriptions for multi-source products to eligible beneficiaries, whether or not they are inscribed by the prescriber as no-substitution, ordinarily be reimbursed only at the lowest "best available price" for the product. If the pharmacist, at the request of the patient, dispenses a product for which the listed price exceeds BAP, the patient must pay the difference to the dispensing pharmacist. The pharmacist may be reimbursed for a no-substitution

prescription of a higher-priced product only when the prescriber has an approved reason for this. (See recommendation 4.21)

5.4 The Committee therefore recommends that the concept of best available price be maintained, in preference to other forms of definition of reimbursement price to pharmacists.

5.5 The Committee therefore recommends that the price for reimbursement of all drugs in the January, 1991 formulary be rolled back to the price at which they were listed in the December 1986, formulary plus consumer price index increases from December 1986 to January 1991. If the product was not listed in the December 1986 formulary, its January 1991 price should be rolled back to the price at which it was first listed after December 1986, and then increased to a value no greater than that allowed by the increase in the CPI from that date to January 1991. If the CPI adjusted price is higher than the current price, the current price should stand.

5.6 The Committee therefore recommends that, for the period commencing with the formulary which follows the January 1991 formulary and ending in January of 1994, increases of drug prices listed for reimbursement shall not exceed 50 per cent of the consumer price index.

5.7 The Committee therefore recommends that the current legislation be amended, with appropriate sanctions, to strengthen the "best available price" concept so that manufacturers are required to sign a binding agreement to make available that product size on which BAP has been determined, at that listed price, to all pharmacies or wholesalers for the duration of the applicable formulary.

5.8 The Committee further recommends that the Ministry of Health vigorously

pursue allegations of deals and incentives provided by manufacturers in order to immediately reduce the “best available price” accordingly, if the allegations prove true.

5.9 The Committee further recommends that the legislation be amended to prohibit pharmacists from claiming reimbursement (for the cost component of the prescription price) under Ontario Drug Benefit at a level higher than that which was actually paid for the product.

5.10 The Committee also recommends that the legislation be amended to require pharmacists, when dispensing prescriptions for interchangeable products in the non-Ontario Drug Benefit marketplace, to charge for the cost component of the prescription price the amount that was actually paid for the product if this amount was less than the best available price.

## Chapter VI Distribution of Drugs

6.1 The Committee therefore recommends that minimum standards be established for services provided by wholesalers, in order for their charges to qualify for reimbursement as set forth below in recommendation 6.2. These standards should include availability and fast, province-wide distribution of most prescribed products.

6.2 The Committee therefore recommends that, immediately upon consideration of these recommendations, the Ministry of Health permit wholesalers to enter into agency distribution agreements with manufacturers.

6.3 The Committee further recommends that, to coincide with the effective date of the current renegotiation of the pharmacists’ fee, the Ministry of Health take appropriate steps to reduce the percentage added to the best available price to a level designed to compensate for

the actual amount the pharmacist must pay to the wholesaler, and to eliminate entirely the upcharge added to BAP for direct sales.

6.4 The Committee therefore recommends that the Ministry of Health take appropriate steps to ensure that no increase in the best available price is allowed when a drug manufacturer moves from indirect to direct sales.

6.5 The Committee therefore recommends that, as part of the current dispensing fee negotiation, the Ministry of Health renegotiate the fee structure by which pharmacists are reimbursed to reflect the reduced upcharge and the expanded professional role for pharmacists.

6.6 The Committee therefore recommends that, by the end of 1992, provincial psychiatric hospitals be allowed to utilize the Ontario Hospital Association’s group purchasing plan.

6.7 The Committee therefore recommends that an outside group of consultants be engaged to conduct a comprehensive management and operational audit of the services provided by Government Pharmacy with the express purpose of:

- a) examining the possibility of the Ministry of Health divesting itself of the purchasing, warehousing and distribution of pharmaceutical products being carried on through either Government Pharmacy or the supply and services branch, in order that these functions be handled through private sector services which now exist or may be developed; or
- b) examining the possibility of developing a more efficient operation of the existing system; and
- c) developing, with the involvement of the organizations themselves, more efficient alternatives to those services currently provided to long-term care facilities; and



d) examining the establishment of an outside board of directors from the private sector to oversee the operation should it be retained in some form.

6.8 The Committee therefore recommends that unit dose/IV admixture programs be identified as the system of choice for institutional drug delivery in hospitals above a certain size.

6.9 The Committee further recommends that by 1991 the Ontario Ministry of Health and the Ontario Hospital Association determine the size and other relevant requirements, and that those hospitals identified receive funding for the conversion to a unit dose system.

## Chapter VII The Prescribing of Drugs

7.1 The Committee therefore recommends that, as an integral part of optimal therapy, rational pharmacotherapy should be the goal for all concerned with the use of prescription drugs in Ontario.

7.2 The Committee therefore recommends that the Ministry of Health invite the pharmaceutical industry to jointly investigate the possibility of shared funding for an Ontario centre for the study of drug prescribing. It would be attached to one health science centre, with linkages to practising physicians through the Royal College of Physicians and Surgeons of Canada, the College of Family Practice of Canada and the Ontario Medical Association, and to departments of clinical pharmacology that, we believe, should be established in each Ontario faculty of medicine. (See recommendation 7.17.)

7.3 The Committee therefore recommends to the College of Physicians and Surgeons of Ontario and the Ontario Medical Association, that individual prescribers be encouraged to remain advocates for, and

responsible to, individual patients.

Organized medicine, on the other hand, has a role in protecting society's resources .

7.4 The Committee therefore recommends that the Ontario Medical Association and the College of Physicians and Surgeons of Ontario, with input from the Ontario Pharmacists' Association and the Ontario College of Pharmacists, jointly study the appropriateness of the quantity of drugs on a prescription and issue appropriate guidelines.

7.5 The Committee therefore recommends that the Council of Ontario Faculties of Medicine encourage educational initiatives at each of Ontario's medical schools to include:

- a) Pilot studies to determine the effectiveness of changes in undergraduate and postgraduate curricula which emphasize the cultivation and maintenance of good prescribing practices;
- b) Greater integration of basic and clinical sciences, in particular integration of pharmacotherapy with pharmacology;
- c) Greater recognition by clinical specialist departments of the differences in the pattern and types of morbidity found in university teaching hospitals and community practice;
- d) More emphasis on critical appraisal of drug products throughout the medical curriculum; and
- e) More emphasis on the specific medical problems and treatment needs of the elderly. (See also chapter 11.)

7.6 The Committee therefore recommends that educational initiatives at the medical postgraduate level include:

- a) Regular review of pharmacological aspects of therapy;

- b) Improved integration of clinical pharmacology in all services including surgical units;
- c) Improved audit procedures regarding the use of drug products (see also drug utilization review); and
- d) A specific geriatric experience at either intern and/or residency level.

7.7 The Committee therefore recommends that:

- a) The Council of Ontario Faculties of Medicine, the Ontario Medical Association and the College of Physicians and Surgeons of Ontario be asked, by 1991, to develop new, imaginative and effective programs in continuing medical education which will encourage participation of a greater proportion of physicians; and
- b) That the Council of Ontario Faculties of Medicine, in conjunction with the Drug Quality and Therapeutics Committee, the Pharmaceutical Manufacturers Association of Canada, the Canadian Drug Manufacturers Association, Health and Welfare Canada, Canadian Pharmaceutical Association and the Ministry of Health be asked to develop, by 1993, innovative post-marketing surveillance studies, of a variety of pharmaceutical preparations, both brand names and generics, and involving large numbers of family practitioners.

7.8 The Committee therefore recommends the development, by the profession of medicine, through its various organizations, of appropriate guidelines to treatment.

7.9 The Committee therefore recommends that "Choice of Medications—1990" be published and made available, on an annual basis, to all licensed physicians and pharmacies in Ontario. The publication should contain guidelines for prescribing

based upon objective information about preferred drug products, including their indications, contraindications, side effects, recommended dosages and relative costs.

7.10 The Committee therefore recommends that the Ministry of Health continue to be guided by the DQTC as it develops the "restricted use" concept in the Ontario Drug Benefit formulary. (See also recommendations 4.2 and 4.3.)

7.11 The Committee therefore recommends that the Ontario Hospital Association be asked to foster the continued development and use of restricted hospital formularies.

7.12 The Committee therefore recommends that the Ministry of Health, the Ontario Medical Association and the Ontario Pharmacists' Association promote the extension of the restricted formulary approach to group clinics, nursing and old age homes, health maintenance organizations and comprehensive health organizations.

7.13 The Committee therefore recommends that the use in Ontario of non-proprietary (generic) drug product names be encouraged in the writing and labelling of prescriptions, except where there is a special reason to use a brand name.

7.14 The Committee therefore recommends that the Council of Ontario Faculties of Medicine, the College of Physicians and Surgeons of Ontario, and the Ontario Medical Association be asked to promote regular, appropriate, organized reviews of drug treatment.

7.15 The Committee therefore recommends that, by 1992, the Ministry of Health establish pilot projects to test unbiased detailing in Ontario, based on the Harvard model. Consultation with the Ontario College of Pharmacists, the Ontario Pharmacists' Association, the College of Physicians and Surgeons, the Ontario Medical Association

and the pharmaceutical industry should precede this.

7.16 The Committee therefore recommends that, by 1991, the College of Physicians and Surgeons of Ontario, after consultation with the Ontario Medical Association and the pharmaceutical industry, develop and publicize ethical guidelines for physician/industry interaction, which also deal with the industry's involvement in continuing medical education.

7.17 The Committee therefore recommends that the Ministry of Colleges and Universities be asked to promote and fund the establishment of a department of clinical pharmacology in each Ontario medical school. These should be closely linked to the centre for the study of drug prescribing (see recommendation 7.2.)

7.18 The Committee therefore recommends that the Ontario Medical Association, the Ontario branch of the Canadian Society of Hospital Pharmacists and the Ontario Pharmacists' Association be asked to establish formal mechanisms, at provincial and local levels, that will increase professional liaison, as necessary, on the issues of patient counselling and communication, as well as other issues of mutual concern. We suggest that emphasis be placed on liaison at the community level on an individual and group basis.

7.19 The Committee therefore endorses the recommendation of the Task Force on the Use and Provision of Medical Services (Scott Task Force) to establish the Ontario Council on Health Technology Assessment, and recommends that as one of its tasks, that body evaluates new, high-cost drugs.

7.20 The Committee therefore recommends that the DQTC be asked to review all the over-the-counter preparations that are currently benefits of the Ontario Drug Benefit

plan in the same way that it reviews other prescription products, and that the over-the-counter preparations which are to be listed in the formulary be allocated to either the general or restricted use category.

## Chapter VIII Dispensing/ Administration

8.1 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists clearly defines the respective roles of auxiliary personnel and pharmacists and ensures that assistants perform technical, product-oriented tasks while pharmacists concentrate on patient-oriented tasks such as monitoring drug therapy and providing advice on drugs to patients and other health care professionals. The strategies used to ensure this implementation should be associated with the promulgation of standards of practice and competence assurance.

8.2 The Committee therefore recommends that, by the end of 1992, the Ministry of Health, the Ontario College of Pharmacists and the Ontario Pharmacists' Association jointly devise requirements for information management systems, and guidelines for their use, which will ensure optimal access to patient profiles, and adverse drug interaction programs. In addition, the Committee recommends that the Ontario College of Pharmacists establish practice guidelines to implement the optimal use of this type of information management system.

8.3 The Committee therefore recommends that, by the end of 1990, standards be established for pharmaceuticals introduced in what is known as "dispensing size" or "original pack" packages. The standards should ensure that no original package dispensed should create uncertainty or confusion, be a hindrance to individualized treatment regimens, impede interchange-



ability of drug products (for purposes of interchangeability, physical characteristics of packages should not be regarded as unique) or be a marketing or promotional tool (promotion to the public of a particular brand should not be a feature of design or labelling.) In addition, the packages should be required to meet child resistant standards.

8.4 The Committee further recommends that the Ministry of Health, in consultation with appropriate interested organizations, promptly undertake discussions with the Health Protection Branch of Health and Welfare Canada to establish these standards.

8.5 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists establish a working group for the express purpose of expanding the practise of providing auxiliary labels and other printed information on prescription drugs, along with verbal reinforcement to the patient by the pharmacist. The working group should include consumer representation.

8.6 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists encourage the profession to pay particular attention to the needs of visually handicapped patients by using large type, and appropriate inserts and graphics whenever possible, in the preparation of prescription labelling.

8.7 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists encourage the use of labels and other directions in the language familiar to the patient, with the pharmacist providing appropriate verbal reinforcement.

8.8 The Committee therefore recommends that, by the end of 1990, the Ministry of

Health conduct an education campaign, directed primarily at seniors, recommending that patients select a pharmacy and, in so far as this is practical, obtain all pharmacy services there.

8.9 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists enforce this voluntary trend through regulations requiring all pharmacies to maintain patient medication profiles in compliance with defined content standards.

8.10 The Committee therefore recommends that the Ontario College of Pharmacists, the Ontario Pharmacists' Association, the Ministry of Health and other interested parties diligently pursue the development of portable patient medication records such as the "smart card."

8.11 The Committee therefore recommends that, by the end of 1990, the Ontario Medical Association, the College of Physicians and Surgeons of Ontario, the Royal College of Dental Surgeons of Ontario, the Ontario Pharmacists' Association, and the Ontario College of Pharmacists devise guidelines to ensure that the pharmacist, when clinically appropriate and with the agreement of the patient, has access to the patient's diagnosis(es.)

8.12 The Committee therefore recommends that, by the end of 1990, the Ministry of Health, in co-operation with appropriate interested organizations such as the Ontario Pharmacists' Association and the Ontario College of Pharmacists, launch a campaign to make the public more aware of the services that can be expected of a pharmacist, with emphasis on those related to the provision of information on the proper use of medications.

8.13 The Committee therefore recommends that the Ontario College of Pharmacists

require all pharmacies in Ontario, by the end of 1991, to have an appropriate consultation area where patients can discuss their medication with a pharmacist, in privacy and in relative comfort.

8.14 The Committee also recommends that pharmacists exercise more personal control over the sale of non-prescription drugs and that, by the end of 1991, the Ontario College of Pharmacists require all pharmacies in Ontario to have a professional products area, adjacent to or contiguous with the dispensary, where all non-prescription drugs—with the exception of Schedule “C” drugs which must not be available for self-selection—must be located.

8.15 The Committee therefore recommends that, by the end of 1991, the Ontario College of Pharmacists require the use of signs and printed material within the pharmacy to alert the public to the importance of consulting a pharmacist regarding the use of non-prescription drugs, especially when these are taken concurrently with prescription drugs.

8.16 The Committee therefore recommends that, by the end of 1991, the Ministry of Health, in cooperation with the Ontario Pharmacists' Association, establish pilot projects to examine and assess alternative reimbursement and payment mechanisms which would reward the provider of professional pharmaceutical services and be independent of the sale or dispensing of a drug.

8.17 The Committee therefore recommends that, by the end of 1992, the Ministry of Health, in conjunction with the Ontario Pharmacists' Association, the Ontario College of Pharmacists and the Ontario Hospital Association, create a linkage between patient medication files in community and hospital pharmacies and ensure that pre-hospitalization or discharge consultations stress the importance to the patient of such an exchange of information.

8.18 The Committee therefore recommends that the Ministry of Health, in conjunction with the Ontario Hospital Association, the Ontario Medical Association, the Ontario Pharmacists' Association, the Canadian Society of Hospital Pharmacists (Ontario branch), and the Ontario College of Pharmacists immediately encourage the expansion of the clinical role of pharmacists in the increased use of formularies, pharmacotherapy consultation, drug therapy monitoring and subsequent intervention when necessary.

8.19 The Committee therefore recommends that, by the end of 1992, the ministries of Health and Community and Social Services, in cooperation with the Ontario Medical Association, the Ontario Nursing Home Association, the Ontario Association of Non-Profit Homes and Services for Seniors, the Ontario Pharmacists' Association and the Ontario College of Pharmacists, set up pilot projects which involve community drug therapy committees based on models existing in institutional settings.

8.20 The Committee therefore recommends that, by the end of 1990, the Ministry of Health and the Ontario College of Pharmacists ensure that drug information programs are encouraged, supported, coordinated and expanded to other professionals.

8.21 The Committee therefore recommends that, by the 1992 academic year, or the year a new faculty of pharmacy starts operations (see recommendation 8.22), the faculty of pharmacy, University of Toronto, reduce its enrolment to the level for which it was designed.

8.22 The Committee therefore recommends that, by the 1992 academic year, the Ministry of Colleges and Universities establish a second faculty of pharmacy in Ontario, with an enrolment approximating the reduced level of the Toronto faculty.

This should be a five year program similar to that recommended for the University of Toronto (see recommendation 8.23), established at an Ontario university that has a health sciences program which includes medicine. The decision to establish this faculty should take into consideration the need for such services in northern Ontario, but the Committee believes the advantages of having faculties of both medicine and pharmacy at the same location outweigh geographic concerns.

8.23 The Committee therefore recommends that, by the 1991 academic year, the University of Toronto embark on a five year undergraduate pharmacy program to permit more structured practical training and increased instruction in communications, patient counselling, therapeutics, drug information, pathophysiology and geriatrics.

8.24 The Committee therefore recommends that the practical training program for pharmacy students and interns be structured and form part of the five year program recommended above (see recommendation 8.23.)

8.25 The Committee therefore recommends to the Ministry of Colleges and Universities that, within the next two years, a doctor of pharmacy program be established at an appropriate faculty of pharmacy at an Ontario university.

8.26 The Committee therefore recommends that, by the 1991 academic year, the faculties of medicine and pharmacy at the University of Toronto jointly instruct students in patient-oriented services, including choice of drug therapy, monitoring techniques and patient counselling. This recommendation is also directed to the Ministry of Colleges and Universities and the Council of Ontario Faculties of Medicine as a requirement for the establishment of an additional faculty of pharmacy.

8.27 The Committee therefore recommends that the Ministry of Colleges and Universities reach an early decision regarding the planning of such a health science centre in northern Ontario.

8.28 The Committee therefore recommends that, by the end of 1991, the faculty of pharmacy, University of Toronto, review its curriculum with a view to increasing the emphasis in communications, patient counselling, therapeutics, drug information, pathophysiology and geriatrics. At the same time, the Ontario College of Pharmacists should review its requirements for continuing education to include courses in pharmacology related to geriatrics and paediatrics, as well as courses in drug information, intravenous admixture, radio-pharmacy and total parenteral nutrition.

8.29 The Committee therefore recommends that, by the 1991 academic year, the University of Toronto and the Council of Ontario Universities' Health Science Faculties ensure that training for medical, nursing and pharmacy students include appropriate emphasis on the need to communicate to the patient the importance of proper drug use.

8.30 The Committee therefore recommends that, by 1991, the Ministry of Health, together with the Ontario Hospital Association, the Ontario Association of Non Profit Homes and Services for Seniors and the Ontario Nursing Home Association, review and improve as necessary, medication acquisition, storage, dispensing and administration systems in long term care institutions.

8.31 The Committee therefore recommends that an interdisciplinary committee of the College of Nurses of Ontario, College of Physicians and Surgeons of Ontario and the Ontario College of Pharmacists should be established to determine the appropriate role of the nursing profession in patient counselling.



8.32 The Committee therefore recommends nursing participation in drug utilization review, pharmacy and therapeutics committees.

8.33 The Committee therefore recommends that:

- a) There be more continuing education for nurses regarding optimal pharmacotherapy; and
- b) The College of Nurses of Ontario be asked to re-examine the nursing curriculum to ensure that a sufficient knowledge of basic therapeutics is included to allow meaningful postgraduate study and experience to make the nurse an effective treatment counsellor.

8.34 The Committee therefore recommends that:

- a) The College of Nurses of Ontario clarify and establish standards for basic and continuing education about pharmacotherapy; and
- b) The Ministry of Health budget sufficient funds to its health care organizations to allow them to fund nurses' participation in ongoing education (i.e. paying the cost of education.)

8.35 The Committee therefore recommends that any organization employing a nurse who administers medication should ensure that a suitable problem-solving mechanism is available in case of dispute over the propriety of treatment.

8.36 The Committee therefore recommends that, in all health care institutions in Ontario, mechanisms be put in place to ensure appropriate patient education regarding treatment plans prior to discharge. Adequate time must be budgeted to allow for this and if it is to be done by nurses then adequate resources must be available to

assure the nurse appropriate and ongoing education about pharmacotherapy issues.

8.37 The Committee therefore recommends that, by the end of 1990, the Ontario College of Pharmacists, the Ontario Branch of the Canadian Society of Hospital Pharmacists and the Ontario Hospital Association take steps to ensure that all hospital pharmacies require patient medication profiles in compliance with defined content standards.

8.38 The Committee therefore recommends that the Ministry of Health and the Ontario Hospital Association review the rationale behind the reimbursement policy for Ontario Drug Benefit prescriptions dispensed for hospital outpatients.

8.39 The Committee therefore recommends that by 1991, the Ministry of Health, in cooperation with the Ontario Hospital Association, establish mechanisms to adequately compensate hospitals providing professional pharmacy services to outpatients.

8.40 The Committee therefore recommends that total parenteral nutrition, intravenous antibiotic, analgesic and other home care drug programs be enhanced and expanded through an incentive reimbursement program to be negotiated by 1991 by the Ministry of Health, the Ontario Hospital Association, the Ontario Pharmacists' Association and other interested parties.

8.41 The Committee therefore recommends that by 1991 the Ministry of Health, or other appropriate granting agency, provide the necessary funding to increase both the stipend paid to hospital pharmacy residents and the number of positions available for such residents.

8.42 The Committee therefore recommends that by 1991 the Ontario Hospital Association, the Ontario Medical

Association, the Ministry of Health and the Ontario branch of the Canadian Society of Hospital Pharmacists review the mechanisms for control of investigational drug use for clinical trials in hospitals with a view toward the establishment of standards and ethically appropriate methods of cost containment.

8.43 The Committee therefore recommends that a statutory limitation of liability for administration of medications should be established, in order to relieve associations, and individuals working for such associations under delineated conditions, from liability for administering or monitoring medication in residential settings.

8.44 The Committee therefore recommends that courses in the skills required by health care workers to administer medication and monitor patient compliance in residential settings should be developed and made available through public health care programs.

8.45 The Committee therefore recommends that programs which provide for drug therapy compliance monitoring and drug administration and reminders should be encouraged and funded in community and public health programs.

8.46 The Committee therefore recommends that drug therapy compliance monitoring programs be included as part of the approved programs developed or implemented by community assessment teams, day hospitals and day care centres.

## Chapter IX Utilization

9.1 The Committee therefore recommends that low income individuals, or individuals with catastrophic drug costs, who do not have coverage through a private health insurance plan, have drug costs covered

through a plan based on an income means test, adjusted for the number of dependents, in accordance with social assistance guidelines, and that copayments should be introduced for individuals and families with incomes above social assistance levels.

9.2 The Committee therefore recommends that recipients of Ontario Drug Benefit plan benefits not on social assistance should be required to participate in the costs of prescriptions. Cost-sharing should be in the form of a fixed charge per prescription of not more than \$4. The maximum amount to be paid by the consumer for prescription drugs in any given year should be \$250 and any drug costs above that amount should be completely covered by the ODB.

9.3 The Committee therefore recommends that the Ministry of Health, in conjunction with the Council of Faculties of Medicine, take the lead in developing, by 1992, pilot drug utilization review programs that can become an important part of continuing medical education. The goals of these projects would be to determine practical and effective ways of improving the quality of drug prescribing and the health status of patients. Such projects should be supported financially, at arms length, by the province. (See also recommendation 4.6.)

9.4 The Committee therefore recommends that an Ontario adverse drug reaction reporting program be continued and that it should be supported by the province.

9.5 The Committee therefore recommends that the governments of Canada, Ontario and the municipalities set up appropriate mechanisms, properly funded and supported, to attempt to reinforce the social unacceptability of drug abuse.

9.6 The Committee therefore recommends that the Ontario Medical Association, the College of Family Practice and the

Addiction Research Foundation should jointly research the various approaches to reducing the overuse of hypnotics, sedatives and tranquillizers.

9.7 That drug products and other medically indicated drug-related therapy (such as necessary enzymes and vitamins) used in the treatment of cystic fibrosis be funded as benefits under the appropriate Ministry of Health program.

9.8 That drug products and medically-related supplies used in the treatment of thalassemia be funded as benefits under the appropriate Ministry of Health program.

## Chapter XI Pharmacotherapy for the Elderly

11.1 The Committee therefore recommends that the Drug Quality and Therapeutics Committee be asked to specifically review the availability of liquid and other formulations of drugs such as iron and acetaminophen for those who have difficulty swallowing or using solid dosage forms.

11.2 The Committee therefore recommends that the smart cards which are to be introduced to facilitate drug utilization, monitoring and review (see recommendation 8.10), be programmed to ensure that problems in pharmacotherapy (e.g. drug interactions) are promptly identified. Electronic communication systems recommended for all pharmacies (see recommendation 8.2) should similarly be programmed to take into account the special problems of prescribing for the elderly. Similar systems should be developed for practising physicians.

11.3 The Committee therefore recommends that the federal Health Protection Branch and the DQTC:

- a) be asked to encourage manufacturers to ensure that, whenever it is relevant and feasible, data from drug trials submitted in support of applications for licensing and listing include data from older individuals so that safety and effectiveness in that population can be assessed. Similarly, Ontario faculties of medicine sponsoring drug trials should be asked to include older subjects whenever this is relevant or feasible; and
- b) be asked to require pharmaceutical manufacturers to provide specific data and recommendations for prescribing for older patients, where this is relevant.

11.4 The Committee therefore recommends that:

- a) The Ministry of Health, with the advice of seniors' organizations, develop guidelines and an information campaign aimed at ensuring that by 1994, all patients, especially the elderly, choose and remain with one personal physician.
- b) The Ontario Medical Association, the Ontario Hospital Association and the College of Physicians and Surgeons of Ontario establish guidelines by 1992 to ensure that specialist physicians and hospital clinics meticulously and expeditiously inform a patient's family physician of suggested alterations in the patient's drug regimen.
- c) The College of Physicians and Surgeons of Ontario, the College of Family Practice, and the Ontario Medical Association establish guidelines, by 1992, to ensure that primary care physicians maintain and regularly update the older patients' medication list. This information should be shared with other professionals caring for the patient.



d) The Ontario Medical Association and the Ontario Hospital Association, in conjunction with seniors' organizations, establish guidelines by 1991 to communicate to physicians the need to require patients on complicated drug regimens to bring all medications to each visit to any doctor or hospital.

11.5 The Committee therefore recommends that, by 1992, the College of Physicians and Surgeons of Ontario, the Royal College of Dental Surgeons and the Ontario Medical Association develop guidelines in order that prescriptions for hypnotics, sedatives and tranquilizers be issued for the shortest possible time and be clearly marked "no repeats" unless there is a clinical indication to the contrary.

11.6 The Committee therefore recommends that all Ontario faculties of medicine be requested to review their undergraduate and postgraduate curricula, by July 1, 1992, to ensure that:

- a) appropriate instruction and experience are provided in prescribing for the elderly, emphasizing the differences from prescribing for younger patients; and
- b) all family medicine and specialty postgraduate training programs have specific rotations in geriatric medicine, as appropriate, including supervised pharmacotherapy experience in ambulatory and long-term, as well as acute care settings.

11.7 The Committee therefore recommends that the Ontario Medical Association be asked to review, by January 1, 1992, the adequacy of continuing medical education courses available to Ontario physicians with respect to all aspects of geriatric medicine and pharmacotherapy for the elderly. The OMA, in collaboration with the Ontario faculties of medicine, should be asked to ensure that educational gaps are filled so that Ontario physicians can readily and regularly update their knowledge and skills with respect to caring for and properly prescribing for the elderly.

11.8 The Committee also recommends that the Royal College of Physicians and Surgeons and the College of Family Practice of Canada be requested to review their educational objectives and requirements with regard to geriatric medical education and pharmacotherapy for the elderly.

11.9 The Committee therefore recommends that the Ministry of Health, in conjunction with the Ontario Hospital Association, the Ontario Association of Non Profit Homes and Services for Seniors and the Ontario Nursing Home Association, require that, by July 1, 1992, all acute care hospitals and geriatric long-term care facilities establish appropriate systems to monitor the pharmacotherapy of elderly patients.



**Les recommandations du rapport  
sont présentées par chapitre;  
tous les chapitres ne renferment  
pas de recommandations.**

**Chapitre IV Le Formulaire et le comité  
d'appréciation des médicaments et des thérapeutiques**

**4.1** Par conséquent, le comité recommande que le Formulaire du Programme de médicaments gratuits de l'Ontario soit conservé, mais qu'il soit modifié en profondeur.

**4.2** Par conséquent, le comité recommande qu'après la publication de l'édition de janvier 1991, le Formulaire soit gelé pour permettre la création d'un formulaire nouveau et allégé. Les avantages cités dans l'édition de janvier 1991 seraient offerts seulement jusqu'à la publication du formulaire allégé; à ce moment, tous les avantages en vigueur prendraient fin et seraient remplacés par les dispositions du nouveau formulaire.

**4.3** Par conséquent, le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques entreprenne immédiatement une révision de tous les produits inscrits actuellement dans le Formulaire, en ce qui a trait à leur efficacité, leur sûreté, leur équivalence et leur coût.

**4.4** Par conséquent, le comité recommande la mise au point de mécanismes permettant

l'inscription de produits pharmaceutiques sous la recommandation du Comité d'appréciation des médicaments et des thérapeutiques, même lorsqu'aucune demande n'a été présentée par le fabricant.

**4.5** Le comité recommande en outre que des dispositions soient prises pour donner au Formulaire un caractère dynamique; les produits provenant de sources multiples et les produits provenant d'une seule source seraient réexaminés régulièrement, pour être conservés, éliminés ou changés de catégorie.

**4.6** Par conséquent, le comité recommande que le ministère de la Santé, en collaboration avec le College of Physicians and Surgeons of Ontario, le Collège royal des chirurgiens dentistes d'Ontario, l'Association des médecins de l'Ontario, l'Ordre des pharmaciens de l'Ontario et l'Ontario Pharmacists' Association, lance d'ici le 1<sup>er</sup> janvier 1992 un programme destiné à surveiller l'utilisation médicamenteuse et accroître la responsabilité des prescripteurs à l'égard de leur pharmacothérapie.

**4.7** Par conséquent, le comité recommande que le développement et l'utilisation de produits de sources multiples sous des formes posologiques non usuelles soient

encouragés lorsque cela est possible, en assemblant et en promulguant des critères permettant l'identification et l'inscription de produits interchangeables sous des formes posologiques ou d'administration non usuelles.

4.8 Par conséquent, le comité recommande que le ministère de la Santé, le College of Physicians and Surgeons of Ontario, le Collège royal des chirurgiens dentistes d'Ontario, l'Association des médecins de l'Ontario et le Council of Faculties of Medicine collaborent à la mise au point de mécanismes en vue de promouvoir la prescription de médicaments d'appellation commune, lorsque cela est pertinent.

4.9 Par conséquent, le comité recommande qu'après l'édition de janvier 1991, le ministère discontinue le système actuel de publication du Formulaire, en vertu duquel des échéances semestrielles sont établies, et mette au point pour le remplacer un système permanent de révision des produits.

4.10 Par conséquent, le comité recommande que l'on retienne les services d'un comité consultatif spécialiste en matière de produits, tel que représenté par le Comité d'appréciation des médicaments et des thérapeutiques actuel, avec des attributions semblables à celles déjà établies, compte tenu des modifications proposées à la recommandation 4.11.

4.11 Par conséquent, le comité recommande que le mandat du Comité d'appréciation des médicaments et des thérapeutiques soit révisé d'ici le 1<sup>er</sup> janvier 1991 et que les points suivants soient examinés :

a) Un mandat élargi permettant une évaluation plus efficace des facteurs de coût des produits pharmaceutiques; et

b) Un mandat élargi, accompagné des ressources appropriées, permettant de surveiller les effets des modifications apportées au Formulaire.

4.12 Par conséquent, le comité recommande que le Ministère et le Comité d'appréciation des médicaments et des thérapeutiques jouent un rôle plus actif en communiquant régulièrement avec les professionnels de la santé pour souligner les avantages du Formulaire et le processus de révision.

4.13 Que le programme d'autorisation spéciale soit discontinué sous sa forme actuelle.

4.14 Que tous les produits pharmaceutiques devant être autorisés aux fins de paiement en vertu du Programme de médicaments gratuits de l'Ontario soient approuvés par le Comité d'appréciation des médicaments et des thérapeutiques. (Voir la recommandation 4.20 sur la période de transition.)

4.15 Que tous les produits pharmaceutiques approuvés aux fins de paiement par le ministère de la Santé soient inscrits dans le Formulaire et que soient précisées les conditions, le cas échéant, auxquelles ils peuvent être couverts en vertu du Programme de médicaments gratuits de l'Ontario.

4.16 Que le Comité d'appréciation des médicaments et des thérapeutiques révise complètement tous les produits pharmaceutiques pour lesquels des autorisations spéciales ont été délivrées. Nous recommandons en outre que ceci soit effectué par ordre de fréquence d'usage (en commençant par le produit le plus couramment utilisé), selon les critères d'inscription au Formulaire. Tous les médicaments approuvés par le Comité d'appréciation des médicaments et des thérapeutiques après cette révision devraient être inscrits dans le



Formulaire. Les médicaments qui ne reçoivent pas l'approbation du comité ne devraient pas être inscrits dans le Formulaire, ni être admissibles aux fins de paiement par le ministère de la Santé.

4.17 Que le Formulaire renferme deux catégories de médicaments : *usage ordinaire* et *usage limité*. Le coût des médicaments *d'usage ordinaire* devrait être remboursé chaque fois qu'ils sont prescrits et dispensés aux personnes admissibles aux programmes de médicaments gratuits de l'Ontario.

L'appellation *usage limité* pourra être accordée aux autres produits pharmaceutiques qui pourront seulement être remboursés à des conditions déterminées par le Comité d'appréciation des médicaments et des thérapeutiques et énoncées dans le Formulaire du programme de médicaments gratuits de l'Ontario. Par exemple, l'appellation *usage limité* peut être accordée lorsqu'au moins une des conditions suivantes est remplie :

- a) lorsque les conditions thérapeutiques limitées, déterminées par le Comité d'appréciation des médicaments et des thérapeutiques et énoncées dans le Formulaire du Programme de médicaments gratuits de l'Ontario, ont été remplies;
- b) lorsque les médicaments *d'usage ordinaire* ont été essayés et se sont révélés inefficaces ou ont causé des effets indésirables chez un patient particulier; et
- c) lorsque des médicaments *d'usage ordinaire* de rechange sont contre-indiqués, en raison d'une thérapie coexistante ou de particularités chez un patient.

Le prescripteur aurait la responsabilité professionnelle de s'assurer que la (les) condition(s) a (ont) été remplie(s).

4.18 Que les conditions et restrictions, le cas échéant, sous lesquelles les médicaments seront autorisés aux fins de remboursement soient clairement indiquées. Ceci peut être fait par des notes en bas de page ou d'autres indications dans le Formulaire.

4.19 Que tous les produits pharmaceutiques pour lesquels des autorisations spéciales ont été délivrées dans le passé, après avoir été revus par le Comité d'appréciation des médicaments et des thérapeutiques, se retrouvent dans seulement une des catégories suivantes :

- a) Inscription dans le Formulaire avec l'appellation *usage ordinaire*;
- b) Inscription dans le Formulaire avec l'appellation *usage limité*; et
- c) Inadmissibilité à un remboursement par le gouvernement de l'Ontario.

4.20 Que pendant la période de transition, jusqu'à ce que le Comité d'appréciation des médicaments et des thérapeutiques ait pu réviser les médicaments pour lesquels des autorisations spéciales ont été délivrées, tous les médicaments sous autorisation spéciale en instance de révision puissent conserver leur autorisation spéciale. On devrait toutefois imposer un strict moratoire sur l'attribution de l'appellation autorisation spéciale à de nouveaux produits.

4.21 Que le Comité d'appréciation des médicaments et des thérapeutiques crée un mécanisme lui permettant d'étudier rapidement les nouveaux produits présentant des progrès thérapeutiques majeurs.

4.22 Par conséquent, le comité recommande que, bien que la ligne de conduite actuelle de l'Ontario sur l'interchangeabilité des médicaments, qui encourage la substitution par des produits d'appellation commune et la compétitivité en matière de prix, soit maintenue.

- a) L'Ordre des pharmaciens d'Ontario demande aux pharmaciens de renouveler les ordonnances avec les produits dispensés initialement lorsque leur prix est équivalent à celui de produits concurrentiels. (Il est entendu que, lorsqu'il existe une différence substantielle de prix, les pharmaciens dispenseront le produit pharmaceutique à un prix correspondant au niveau auquel ils seront remboursés.)
- b) Les ordonnances sans substitution ne soient plus admises au titre du Programme de médicaments gratuits de l'Ontario; lorsque le patient demande que le produit spécifiquement prescrit soit dispensé, il devrait combler l'écart de prix par rapport au produit le moins coûteux pour lequel le pharmacien sera remboursé.
- c) Le ministère de la Santé, sur l'avis du Comité d'appréciation des médicaments et des thérapeutiques, établisse un mécanisme par lequel un médecin peut demander qu'un produit particulier soit admis à titre de bénéfice (le coût du produit serait entièrement remboursable au pharmacien) dans les très rares cas où un patient ne peut tolérer le produit le moins cher ou en bénéficier.
- d) Les lignes de conduite et, au besoin, la législation soient modifiées afin d'exiger que les pharmaciens informent les patients et les prescripteurs de la substitution d'un produit.
- e) Lorsqu'une nouvelle préparation d'appellation commune entre en usage

général, le ministère de la Santé exige que le fabricant du produit d'appellation commune diffuse l'information nécessaire aux prescripteurs, tout comme le font maintenant les fabricants de produits novateurs.

4.23 Par conséquent, le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques soit habilité à examiner les demandes et à faire des recommandations au ministre de la Santé concernant l'interchangeabilité des produits pharmaceutiques, indépendamment de la situation des produits au titre du Programme de médicaments gratuits de l'Ontario. Si l'on juge nécessaire de changer la législation ou les règlements pour que cela soit possible, le changement approprié devrait être institué.

## Chapitre V L'acquisition des médicaments

5.1 Par conséquent, le comité recommande que le gouvernement de l'Ontario prenne l'initiative de promouvoir des ententes fédérale-provinciales et interprovinciales en vue d'une ligne de conduite sur l'interchangeabilité à l'échelle du pays. Santé et Bien-être social Canada devrait se voir confier un mandat plus vaste : en plus de confirmer la sûreté et l'efficacité des produits pharmaceutiques, le processus d'approbation devrait également déterminer si le produit est bioéquivalent à d'autres produits approuvés et s'il est interchangeable avec eux.

5.2 Par conséquent, le comité recommande que l'équivalent sous appellation commune d'un produit de marque commerciale ne soit pas inscrit dans le formulaire pour la première fois à un prix supérieur à 60 p. 100 du prix de référence du produit de marque commerciale équivalent. Ce prix de référence sera le prix inscrit du produit de marque commerciale rencontré dans le

formulaire antérieur à celui où le produit d'appellation commune est censé être inclus pour la première fois.

5.3 Par conséquent, le comité recommande que toutes les ordonnances pour des produits de sources multiples à l'intention de prestataires admissibles, indépendamment de leur désignation de produit «sans substitution» par le prescripteur, soient ordinairement remboursés uniquement au «meilleur prix disponible» le plus bas pour le produit. Si le pharmacien, à la demande du patient, dispense un produit dont le prix inscrit dépasse le MPD, le patient devra payer la différence au pharmacien. Le pharmacien peut être remboursé pour une ordonnance «sans substitution» mettant en cause un produit plus coûteux, seulement si le prescripteur a une raison approuvée d'avoir prescrit le produit. (Voir la recommandation 4.21.)

5.4 Par conséquent, le comité recommande que le concept du meilleur prix disponible soit conservé, de préférence à d'autres formes de définition du prix de remboursement aux pharmaciens.

5.5 Par conséquent, le comité recommande que le prix de remboursement de tous les médicaments dans le formulaire de janvier 1991 soit ramené aux prix inscrits dans le formulaire de décembre 1986, plus les augmentations de l'indice des prix à la consommation de décembre 1986 à janvier 1991. Si le produit n'était pas inscrit dans le formulaire de décembre 1986, son prix de janvier 1991 devrait être ramené au prix auquel il a été inscrit pour la première fois après décembre 1986, puis augmenté d'un montant ne pouvant pas dépasser l'augmentation de l'IPC entre cette date et janvier 1991. Si le prix ajusté en fonction de l'IPC est supérieur au prix actuel, le prix actuel devrait être maintenu.

5.6 Par conséquent, le comité recommande que, pour la période commençant avec le Formulaire suivant le formulaire de janvier 1991 et se terminant en janvier 1994, l'augmentation des prix des médicaments inscrits aux fins de remboursement ne dépasse pas 50 p. 100 de l'indice des prix à la consommation.

5.7 Par conséquent, le comité recommande que la législation actuelle soit amendée, avec des sanctions appropriées, pour renforcer le concept du meilleur prix disponible, de sorte qu'on exige des fabricants qu'ils signent une entente irrévocable les obligeant à offrir le format du produit à partir duquel le MPD a été établi, au prix inscrit, à toutes les pharmacies et à tous les grossistes, pendant la durée du Formulaire pertinent.

5.8 Le comité recommande en outre que le ministère de la Santé poursuive énergiquement les allégations de transactions ou de primes offertes par le fabricant, afin de réduire immédiatement le MPD en conséquence, si les allégations sont vraies.

5.9 Le comité recommande également que la législation soit amendée afin d'empêcher les pharmaciens de demander un remboursement (pour la portion du prix de l'ordonnance représentant le coût) en vertu du Programme de médicaments gratuits de l'Ontario, à un niveau supérieur au prix réellement payé pour le produit.

5.10 Le comité recommande en outre que la législation soit amendée de manière à exiger que les pharmaciens, lorsqu'ils dispensent des ordonnances pour des produits interchangeables dans les cas de non-admissibilité au Programme de médicaments gratuits de l'Ontario, réclament pour la portion du prix de l'ordonnance représentant le coût du montant qu'ils ont payé réellement pour le produit, si celui-ci était inférieur au meilleur prix disponible.



## Chapitre VI La distribution des médicaments

6.1 Par conséquent, le comité recommande l'établissement de normes minimums pour les services fournis par les grossistes, afin que leurs frais soient admissibles à des remboursements, comme le précise la recommandation 6.2 ci-dessous. Ces normes devraient comprendre la disponibilité ainsi que la distribution rapide et à l'échelle de la province de la plupart des produits de prescription.

6.2 Par conséquent, le comité recommande que, tout de suite après avoir considéré ces recommandations, le ministère de la Santé permette aux grossistes de conclure des ententes de distributeur-agent avec les fabricants.

6.3 Le comité recommande en outre que, pour coïncider avec la date d'entrée en vigueur des honoraires des pharmaciens, qui font actuellement l'objet de nouvelles négociations, le ministère de la Santé prenne des mesures appropriées pour ramener le pourcentage ajouté au meilleur prix disponible à un niveau destiné à dédommager le pharmacien du montant réel qu'il doit payer au grossiste, et pour éliminer complètement le supplément ajouté au MPD pour les ventes directes.

6.4 Par conséquent, le comité recommande que le ministère de la Santé prenne les mesures appropriées pour empêcher toute augmentation du meilleur prix disponible lorsqu'un fabricant de médicaments passe des ventes indirectes aux ventes directes.

6.5 Par conséquent, le comité recommande que dans le cadre de la négociation actuelle sur les honoraires de dispensation, le ministère de la Santé renégocie la structure des honoraires selon laquelle les pharmaciens sont remboursés, pour refléter la diminution du supplément et l'élargissement du rôle professionnel du pharmacien.

6.6 Par conséquent, le comité recommande que, d'ici la fin de 1992, les hôpitaux psychiatriques soient autorisés à utiliser le plan d'achat de groupe de l'Ontario Hospital Association.

6.7 Par conséquent, le comité recommande qu'on retienne les services d'un groupe d'experts-conseils indépendants pour effectuer une vaste vérification de l'organisation et de l'exploitation des services fournis par la Pharmacie du gouvernement, expressément dans le but de :

- a) étudier la possibilité que le ministère de la Santé se départisse des fonctions d'acquisition, d'entreposage et de distribution des produits pharmaceutiques, qui sont remplies actuellement par la Pharmacie du gouvernement ou par la Direction de l'approvisionnement et des services, de sorte que ces fonctions soient exécutées par des services du secteur privé, qui existent actuellement ou qui pourront être mis sur pied; ou
- b) étudier la possibilité d'améliorer l'efficacité de fonctionnement du système actuel; et
- c) développer, avec la participation des groupements intéressés, des solutions de rechange plus efficaces aux services offerts actuellement aux établissements de soins de longue durée; et
- d) étudier la création d'un conseil d'administration indépendant provenant du secteur privé pour en surveiller l'exploitation, si on décide de la conserver, sous une forme ou une autre.

6.8 Par conséquent, le comité recommande que les programmes pour la dose unitaire/mixtion intraveineuse soient adoptés comme système de prédilection pour la délivrance de médicaments dans les hôpitaux d'une certaine grosseur.

6.9 Par conséquent, le comité recommande en outre que, d'ici 1991, le ministère de la Santé de l'Ontario et l'Ontario Hospital Association déterminent la grosseur et les autres conditions pertinentes, et que les hôpitaux identifiés reçoivent des subventions pour se convertir au système de dose unitaire.

## Chapitre VII La prescription médicamenteuse

7.1 Par conséquent, le comité recommande qu'en tant que partie intégrante d'une thérapie optimale, la pharmacothérapie judicieuse devrait être l'objectif de toutes les parties s'intéressant à l'usage des produits de prescription en Ontario.

7.2 Par conséquent, le comité recommande que le ministère de la Santé invite l'industrie pharmaceutique à examiner conjointement la possibilité de partager le financement d'un centre ontarien pour l'étude de la prescription médicamenteuse. Il serait rattaché à un centre des sciences de la santé et aurait des liens avec des médecins praticiens, par l'entremise du Collège royal des médecins et chirurgiens du Canada, du Collège des médecins de famille du Canada et de l'Association des médecins de l'Ontario, ainsi qu'avec les départements de pharmacologie clinique qui, selon nous, devraient être créés dans chacune des facultés de médecine en Ontario. (Voir la recommandation 7.17)

7.3 Par conséquent, le comité recommande au College of Physicians and Surgeons of Ontario et à l'Association des médecins de l'Ontario d'encourager les prescripteurs à se faire les défenseurs de leurs patients et à être responsables devant eux. D'autre part, la profession médicale a un rôle à jouer dans la protection des ressources de la société.

7.4 Par conséquent, le comité recommande que l'Association des médecins de l'Ontario et le College of Physicians and Surgeons of Ontario, avec la participation de l'Ontario Pharmacists' Association et de l'Ordre des pharmaciens de l'Ontario, étudient conjointement à quel point la quantité de médicaments prescrits dans une ordonnance est pertinente et émettent des lignes de conduite appropriées.

7.5 Par conséquent, le comité recommande au Council of Ontario Faculties of Medicine d'encourager chacune des écoles de médecine de l'Ontario à prendre les mesures suivantes en matière d'enseignement :

- a) Des études pilotes pour déterminer l'efficacité des modifications apportées dans les programmes d'enseignement de premier cycle et de deuxième et troisième cycles mettant l'accent sur l'acquisition et le maintien de bonnes habitudes de prescription médicamenteuse;
- b) Une meilleure intégration des sciences de base et des sciences cliniques, en particulier l'intégration de la pharmacothérapie à la pharmacologie;
- c) Une meilleure reconnaissance par les départements de spécialités cliniques des différences quant aux modèles et aux types de morbidité rencontrés dans les hôpitaux d'enseignement et dans les centres de médecine communautaire;
- d) Une plus grande importance de l'évaluation critique des produits pharmaceutiques dans les programmes d'enseignement de la médecine; et
- e) Une plus grande importance des besoins particuliers des personnes âgées en matière de traitement de problèmes médicaux (Voir aussi la section 11)

7.6 Par conséquent, le comité recommande que les mesures en matière d'enseignement médical de deuxième et troisième cycle comprennent :

- a) L'examen régulier des aspects pharmacologiques de la thérapie;
- b) Une meilleure intégration de la pharmacologie clinique dans tous les services, y compris les blocs de chirurgie;
- c) L'amélioration des méthodes de vérification quant à l'utilisation des produits de prescription; (Voir également la révision sur l'utilisation médicamenteuse); et
- d) Une expérience particulière en gériatrie, au moment de l'internat ou de la résidence.

7.7 Par conséquent, le comité recommande que:

- a) Le Council of Ontario Faculties of Medicine, l'Association des médecins de l'Ontario et le College of Physicians and Surgeons of Ontario soient invités, d'ici 1991, à développer des programmes en formation médicale permanente qui soient nouveaux, innovateurs et efficaces, afin d'encourager la participation d'un plus grand nombre de médecins; et
- b) Le Council of Ontario Faculties of Medicine, conjointement avec le Comité d'appréciation des médicaments et des thérapeutiques, l'Association canadienne de l'industrie du médicament, l'Association des fabricants de produits pharmaceutiques, Santé et Bien-être social Canada, l'Association pharmaceutique et le ministère de la Santé de l'Ontario soient invités à développer, d'ici 1993, des études d'observation post-marketing innovatrices sur une diversité de préparations pharmaceutiques, tant des produits de marques de commerce que des produits d'appellation commune, et impliquant un grand nombre de médecins de famille.

7.8 Par conséquent, le comité recommande que la profession médicale développe, par l'entremise de ses nombreuses organisations, des règles de conduite pertinentes en matière de traitement.

7.9 Par conséquent, le comité recommande la publication du répertoire intitulé «Choice of Medications - 1990» et que celui-ci soit mis à la disposition, chaque année, de tous les médecins agréés et à toutes les pharmacies en Ontario. Cette publication devrait contenir des directives pour la prescription basées sur des renseignements objectifs concernant les produits pharmaceutiques préférés, y compris leurs indications, contre-indications, effets secondaires, la posologie recommandée et les coûts relatifs.

7.10 Par conséquent, le comité recommande que le ministère de la Santé continue d'être guidé par le Comité d'appréciation des médicaments et des thérapeutiques dans le développement du concept d'usage limité dans le Formulaire du Programme de médicaments gratuits de l'Ontario. (Voir aussi les recommandations 4.2 et 4.3.)

7.11 Par conséquent, le comité recommande que l'Ontario Hospital Association soit invitée à encourager le développement et l'usage de formulaires limités dans les hôpitaux.

7.12 Par conséquent, le comité recommande que le ministère de la Santé, l'Association des médecins de l'Ontario et l'Ontario Pharmacists' Association encouragent la prolongation de la méthode de formulaires limités pour les cliniques de groupe, les maisons de soins infirmiers, les foyers pour personnes âgées, les organisations de maintien de la santé et les organisations de médecine globale.



7.13 Par conséquent, le comité recommande qu'en Ontario, l'usage des noms d'appellation commune des produits pharmaceutiques soit encouragé dans la rédaction des ordonnances et l'étiquetage des médicaments, sauf lorsqu'il existe une raison spéciale d'utiliser un nom de marque de commerce.

7.14 Par conséquent, le comité recommande que le Council of Ontario Faculties of Medicine, le College of Physicians and Surgeons of Ontario et l'Association des médecins de l'Ontario soient invités à faire la promotion de révisions régulières, pertinentes et cohérentes aux pharmacothérapies.

7.15 Par conséquent, le comité recommande que, d'ici 1992, le ministère de la Santé mette sur pied des projets pilotes pour mettre à l'épreuve des façons impartiales de faire des présentations sur les produits en Ontario, d'après le modèle de Harvard. Ceci devrait être précédé par des consultations avec l'Ordre des pharmaciens de l'Ontario, l'Ontario Pharmacists' Association, le College of Physicians and Surgeons of Ontario, l'Association des médecins de l'Ontario et l'industrie pharmaceutique.

7.16 Par conséquent, le comité recommande que, d'ici 1991, le College of Physicians of Ontario, après avoir consulté l'Association des médecins de l'Ontario et l'industrie pharmaceutique, développe et publie des règles d'éthique pour guider les rapports entre les médecins et l'industrie, ces règles portant également sur la participation de l'industrie à l'éducation médicale permanente.

7.17 Par conséquent, le comité recommande que le ministère des Collèges et Universités soit invité à promouvoir et à financer la mise sur pied d'un département de pharmacologie clinique dans chaque école de médecine de l'Ontario. Ils devraient être étroitement rattachés au centre pour l'étude de la prescription médicalementeuse. (Voir la recommandation 7.2)

7.18 Par conséquent, le comité recommande que l'Association des médecins de l'Ontario, la Société canadienne des pharmaciens d'hôpitaux (section de l'Ontario) et l'Ontario Pharmacists' Association soient invités à créer des mécanismes officiels, aux niveaux provincial et local, qui renforceront les liens professionnels sur les questions relatives à la consultation et la communication avec les patients, ainsi que sur d'autres questions d'intérêt commun. Nous suggérons de mettre l'accent sur la liaison au niveau communautaire, entre particuliers et dans des groupes.

7.19 Par conséquent, le comité endosse la recommandation du groupe d'étude sur la consommation médicale et la prestation des soins médicaux (groupe d'étude Scott) pour la création du Conseil de l'Ontario sur l'évaluation de la technologie médicale, et recommande que parmi ses fonctions, cet organisme examine les nouveaux médicaments très coûteux.

7.20 Par conséquent, le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques soit invité à réviser tous les produits grand public au titre du Régime de médicaments gratuits de l'Ontario, comme il le fait pour les autres produits de prescription, et que tous les produits grand public inscrits dans le formulaire soient classés parmi les médicaments à usage général ou à usage limité.

## Chapitre VIII - Délivrance/administration

8.1 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario définisse clairement les rôles respectifs du personnel auxiliaire et des pharmaciens et qu'il s'assure que les aides effectuent les tâches techniques, axées sur le produit, tandis que les pharmaciens se concentrent sur les tâches axées sur le patient, par exemple surveiller la pharmacothérapie et donner des conseils sur les médicaments aux patients et à d'autres professionnels de la santé. Les stratégies utilisées pour en assurer l'application devraient être associées à la promulgation de normes en matière d'exercice et d'assurance de la compétence.

8.2 Par conséquent, le comité recommande que, d'ici la fin de 1992, le ministère de la Santé, l'Ordre des pharmaciens de l'Ontario et l'Ontario Pharmacists' Association établissent conjointement les exigences portant sur les systèmes de gestion par ordinateur et les directives qui en régissent l'usage, de façon à s'assurer l'accès optimal aux profils des patients et aux programmes relatifs aux interactions indésirables des médicaments. D'autre part, le comité recommande que l'Ordre des pharmaciens de l'Ontario établisse des directives régissant l'exercice en vue de mettre en oeuvre l'utilisation optimale de ce genre de système de gestion des données.

8.3 Par conséquent, le comité recommande que, d'ici la fin de 1990, des normes soient établies pour les produits pharmaceutiques présentés dans ce qu'on appelle des emballages «format délivrance» ou «emballage d'origine». Ces normes devraient assurer qu'aucun emballage d'origine délivré ne devrait créer d'incertitude ou de confusion, gêner les traitements individualisés, entraver l'interchangeabilité des produits pharmaceutiques (aux fins de l'interchangeabilité, les caractéristiques

physiques des emballages ne devraient pas être considérés comme étant uniques), ni constituer un outil de commercialisation ou de promotion (la promotion auprès du public d'une certaine marque ne devrait pas être une caractéristique du graphisme ou de l'étiquetage). Par ailleurs, les emballages devraient obligatoirement répondre aux normes d'un emballage protège-enfants.

8.4 Le comité recommande en outre que le ministère de la Santé, en consultation avec les organismes intéressés appropriés, entame sans tarder des discussions avec la Direction générale de la protection de la santé et Bien-être social Canada pour établir ces normes.

8.5 Par conséquent, le comité recommande que d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario crée un groupe de travail ayant expressément pour but de réaliser l'expansion de la pratique consistant à fournir des étiquettes auxiliaires et d'autres renseignements imprimés sur les produits de prescription, ainsi que le renforcement verbal par le pharmacien à l'intention du patient. Ce groupe de travail devrait inclure un ou des représentants des consommateurs.

8.6 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario encourage la profession à porter une attention toute particulière aux besoins des patients handicapés visuels en utilisant des notices et un graphisme appropriés, à gros caractères, chaque fois que cela est possible dans la préparation de l'étiquetage d'un produit de prescription.

8.7 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario encourage l'utilisation d'étiquettes et d'autres instructions dans la langue que le patient connaît bien, le pharmacien ayant pour responsabilité de donner le renforcement approprié par voie verbale.

8.8 Par conséquent, le comité recommande que, d'ici la fin de 1990, le ministère de la Santé effectue une campagne d'éducation, conçue principalement à l'intention des personnes âgées, et recommandant aux patients de choisir une pharmacie pour y obtenir, dans la mesure du possible, tous les services de pharmacie.

8.9 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario réalise l'application de cette tendance volontaire par des règlements exigeant de toutes les pharmacies qu'elles maintiennent des profils pharmaceutiques des patients, conformément à des normes définies quant à leur teneur.

8.10 Par conséquent, le comité recommande que l'Ordre des pharmaciens de l'Ontario, l'Ontario Pharmacists' Association, le ministère de la Santé et d'autres parties intéressées travaillent diligemment à la mise au point de dossiers transférables concernant les dossiers pharmaceutiques des patients, par exemple sous forme de «cartes à mémoire».

8.11 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Association des médecins de l'Ontario, le College of Physicians and Surgeons of Ontario, le Collège royal des chirurgiens dentistes d'Ontario, l'Ontario Pharmacists' Association et l'Ordre des pharmaciens de l'Ontario élaborent des directives pour s'assurer que le pharmacien, lorsque cela est approprié au point de vue clinique et avec le consentement du patient, ait accès au diagnostic du patient.

8.12 Par conséquent, le comité recommande que, d'ici la fin de 1990, le ministère de la Santé, en collaboration avec les organismes intéressés appropriés, par exemple l'Ontario Pharmacists' Association et l'Ordre des pharmaciens de l'Ontario, organise une campagne pour sensibiliser le

public aux services auxquels on peut s'attendre de la part du pharmacien, en mettant l'accent sur ceux consistant à donner des renseignements sur l'usage approprié des médicaments.

8.13 Par conséquent, le comité recommande que l'Ordre des pharmaciens de l'Ontario exige que, d'ici la fin de 1991, toutes les pharmacies de l'Ontario aient un endroit convenable pour la consultation, où les patients peuvent discuter de leurs médicaments avec un pharmacien, et cela dans l'intimité et dans un confort relatif.

8.14 Le comité recommande en outre que les pharmaciens exercent davantage de contrôle sur la vente des médicaments en vente libre et que, d'ici la fin de 1991, l'Ordre des pharmaciens de l'Ontario exige que toutes les pharmacies de l'Ontario aient un rayon des produits professionnels, adjacent ou contigu à l'officine, où doivent se trouver tous les médicaments en vente libre. [Cette consigne n'inclut pas les médicaments de la liste «C», qui ne doivent pas être disponibles en libre choix.]

8.15 Par conséquent, le comité recommande que, d'ici la fin de 1991, l'Ordre des pharmaciens de l'Ontario exige l'utilisation, dans la pharmacie, d'enseignes et de matériel imprimé pour avertir le public de l'importance qu'il y a à consulter un pharmacien concernant l'emploi des médicaments en vente libre, surtout lorsqu'on les prend en même temps que des produits de prescription.

8.16 Par conséquent, le comité recommande que, d'ici la fin de 1991, le ministère de la Santé, en collaboration avec l'Ontario Pharmacists' Association, établisse des projets pilotes pour examiner et évaluer des mécanismes de remboursement offerts à titre de solution de rechange qui rémunéreraient le fournisseur de services pharmaceutiques professionnels et qui



seraient indépendants de la vente ou de la délivrance d'un médicament.

8.17 Par conséquent, le comité recommande que, d'ici la fin de 1992, le ministère de la Santé, conjointement avec l'Ontario Pharmacists' Association, l'Ordre des pharmaciens de l'Ontario et l'Ontario Hospital Association, crée un lien entre les dossiers pharmaceutiques des patients dans les pharmacies de la communauté et les pharmacies d'hôpital, et qu'ils s'assurent que les consultations qui ont lieu avant l'hospitalisation ou avant le renvoi à domicile du patient soulignent au patient l'importance d'un tel échange de renseignements.

8.18 Par conséquent, le comité recommande que le ministère de la santé, conjointement avec l'Ontario Hospital Association, l'Association des médecins de l'Ontario, l'Ontario Pharmacists' Association, la Société canadienne des pharmaciens d'hôpitaux (section de l'Ontario) et l'Ordre des pharmaciens de l'Ontario encouragent immédiatement l'expansion du rôle clinique des pharmaciens dans l'utilisation accrue des formulaires, de la consultation pharmacocinétique, de la surveillance de la pharmacothérapie et de l'intervention subséquente en cas de besoin.

8.19 Par conséquent, le comité recommande que, d'ici la fin de 1992, les ministères de la Santé et des Services sociaux et communautaires, en collaboration avec l'Association des médecins de l'Ontario, l'Association des maisons de soins infirmiers de l'Ontario, l'Ontario Association of Non Profit Homes and Services for Seniors, l'Ontario Pharmacists' Association et l'Ordre des pharmaciens de l'Ontario, créent des projets pilotes qui font appel aux services de comités communautaires de pharmacothérapie basés sur les modèles existants en établissement.

8.20 Par conséquent, le comité recommande que, d'ici la fin de 1990, le ministère de la Santé et l'Ordre des pharmaciens de l'Ontario s'assurent que l'on encourage, que l'on soutienne et que l'on coordonne les programmes d'information sur les médicaments et qu'on les étende à d'autres professionnels.

8.21 Par conséquent, le comité recommande que, d'ici l'année universitaire 1992, ou au cours de l'année où une nouvelle faculté de pharmacie entrera en fonctions (voir la recommandation 8.22), la Faculté de pharmacie de l'Université de Toronto réduise ses inscriptions au nombre pour lequel elle a été conçue.

8.22 Par conséquent, le comité recommande que, d'ici l'année universitaire 1992, le ministère des Collèges et Universités crée en Ontario une seconde faculté de pharmacie, dont le nombre d'étudiants inscrits serait à peu près équivalent au chiffre réduit de la faculté de Toronto. Il devrait s'agir d'un programme de cinq ans semblable à celui recommandé pour l'Université de Toronto (voir la recommandation 8.23), établi dans une université de l'Ontario possédant un programme de sciences de la santé qui comprend la médecine. Dans la décision de créer cette faculté, on devrait tenir compte du besoin de ces services dans le Nord de l'Ontario, mais le comité croit que les avantages à ce que les facultés de médecine et de pharmacie se trouvent au même endroit ont plus de poids que les considérations géographiques.

8.23 Par conséquent, le comité recommande que, d'ici l'année universitaire 1991, l'Université de Toronto commence un programme d'études de pharmacie de premier cycle de cinq ans, afin de permettre une formation pratique plus structurée et un enseignement accru dans les domaines des communications, de la consultation avec les

patients, de la thérapeutique, de l'information sur les médicaments, de la pathopsychologie et de la gériatrie.

8.24 Par conséquent, le comité recommande que le programme de stages pratiques offert aux étudiants et aux internes en pharmacie soit entièrement structuré et qu'il soit intégré au programme de cinq ans recommandé ci-dessus. (Voir la recommandation 8.23.)

8.25 Par conséquent, le comité recommande au ministère des Collèges et Universités que, au cours des deux prochaines années, un programme de doctorat en pharmacie soit créé dans une faculté de pharmacie appropriée d'une université de l'Ontario.

8.26 Par conséquent, le comité recommande que, d'ici l'année universitaire 1991, les facultés de médecine et de pharmacie de l'Université de Toronto enseignent conjointement les étudiants dans le domaine des services axés sur les patients, y compris le choix de la pharmacothérapie, les techniques de surveillance et la consultation avec les patients. Cette recommandation est également adressée au ministère des Collèges et Universités et au Council of Ontario Faculties of Medicine à titre d'exigence pour la création d'une faculté de pharmacie supplémentaire.

8.27 Par conséquent, le comité recommande que le ministère des Collèges et Universités prenne une décision concernant la planification d'un tel centre des sciences de la santé dans le Nord de l'Ontario.

8.28 Par conséquent, le comité recommande que, d'ici la fin de 1990, la Faculté de pharmacie de l'Université de Toronto révise son programme d'études en vue de mettre davantage l'accent sur les communications, la consultation avec les patients, la théra-

peutique, l'information sur les médicaments, la pathophysiologie et la gériatrie. En même temps, l'Ordre des pharmaciens de l'Ontario devrait réviser ses exigences en matière d'éducation permanente, de façon à y inclure des cours de pharmacologie relatifs à la gériatrie et à la pédiatrie, de même que des cours sur l'information relative aux médicaments, la mixtion intraveineuse, la radiopharmacie et l'alimentation parentérale totale.

8.29 Par conséquent, le comité recommande que, d'ici l'année universitaire 1991, l'Université de Toronto et le Council of Ontario Universities' Health Science Faculties s'assurent que la formation des étudiants en médecine, en soins infirmiers et en pharmacie comprend un volet qui met l'accent, de façon appropriée, sur la nécessité de communiquer au patient l'importance de l'utilisation appropriée des médicaments.

8.30 Par conséquent, le comité recommande que, d'ici 1991, le ministère de la Santé, conjointement avec l'Ontario Hospital Association, l'Ontario Association of Non Profit Homes and Services for Seniors et l'Association des maisons de soins infirmiers de l'Ontario révisent et améliorent au besoin les systèmes d'acquisition, d'entreposage, de délivrance et d'administration des médicaments dans les établissements pour soins de longue durée.

8.31 Par conséquent, le comité recommande la création d'un comité interdisciplinaire, composé de représentants de l'Ordre des infirmières et infirmiers de l'Ontario, du College of Physicians and Surgeons of Ontario, et de l'Ordre des pharmaciens de l'Ontario, des écoles de soins infirmiers, de médecine et chirurgie et de pharmacie, afin de déterminer le rôle approprié de la profession d'infirmier dans la consultation avec les patients.

8.32 Par conséquent, le comité recommande la participation des soins infirmiers aux comités sur la révision de l'utilisation médicamenteuse, la pharmacie et la thérapeutique.

8.33 Par conséquent, le comité recommande que :

- a) L'enseignement permanent des infirmiers concernant la pharmacothérapie optimale soit accru; et
- b) L'Ordre des infirmières et infirmiers de l'Ontario soit invité à réexaminer les programmes d'enseignement en soins infirmiers pour s'assurer qu'ils comprennent des connaissances suffisantes en thérapeutique de base, afin de rendre plus significatives les études et les expériences après l'obtention du diplôme, de sorte que l'infirmier devienne un conseiller plus efficace en matière de traitement.

8.34 Par conséquent, le comité recommande que :

- a) L'Ordre des infirmières et infirmiers de l'Ontario précise et établisse des normes pour l'enseignement de base et l'éducation permanente concernant la pharmacothérapie; et
- b) Le ministère de la Santé budgétise des fonds suffisants pour permettre à ses organisations de soins de santé de financer la participation d'infirmiers à des programmes d'éducation permanente (c.-à-d. les défrayer de leurs dépenses d'éducation).

8.35 Par conséquent, le comité recommande que dans toute organisation où travaille un infirmier administrant des médicaments, il existe un mécanisme approprié pour la recherche de solution dans les cas de désaccord quant à la pertinence des thérapies.

8.36 Par conséquent, le comité recommande que, dans tous les établissements de soins de santé de l'Ontario, on crée des mécanismes pour bien renseigner les patients quant à leur plan de traitement avant leur renvoi à domicile. On doit accorder suffisamment de temps pour ceci; si cette tâche incombe aux infirmiers, il faudra prévoir des ressources adéquates pour leur assurer une formation appropriée et permanente concernant la pharmacothérapie.

8.37 Par conséquent, le comité recommande que, d'ici la fin de 1990, l'Ordre des pharmaciens de l'Ontario, la section de l'Ontario de la Société canadienne des pharmaciens d'hôpitaux et l'Ontario Hospital Association prennent des mesures pour s'assurer que toutes les pharmacies d'hôpitaux exigent des profils pharmaceutiques des patients, conformément à des normes définies quant à leur teneur.

8.38 Par conséquent, le comité recommande que le ministère de la Santé et l'Ontario Hospital Association révisent le raisonnement derrière la ligne de conduite concernant le remboursement des ordonnances au titre du Programme de médicaments gratuits de l'Ontario dispensés aux malades externes des hôpitaux.

8.39 Par conséquent, le comité recommande que d'ici 1991, le ministère de la Santé, en collaboration avec l'Ontario Hospital Association, crée des mécanismes pour compenser adéquatement les hôpitaux offrant des services pharmaceutiques professionnels aux malades externes.

8.40 Par conséquent, le comité recommande que l'alimentation parentérale totale, les antibiotiques administrés par intraveineuse, les analgésiques et les autres programmes concernant les médicaments pour les soins à domicile soient améliorés et élargis, grâce à un programme de



remboursement d'encouragement devant être négocié d'ici 1991 par le ministère de la Santé, l'Ontario Hospital Association, l'Ontario Pharmacists' Association et d'autres parties en cause.

8.41 Par conséquent, le comité recommande que, d'ici 1991, le ministère de la Santé, ou tout autre organisme approprié chargé d'octroyer des subventions, fournisse les fonds nécessaires pour augmenter tant le traitement des résidents en pharmacie dans les hôpitaux que le nombre de postes disponibles pour ces résidents.

8.42 Par conséquent, le comité recommande que d'ici 1991, l'Ontario Hospital Association, l'Association des médecins de l'Ontario, le ministère de la Santé et la section de l'Ontario de la Société canadienne des pharmaciens d'hôpitaux révisent les mécanismes régissant l'utilisation des médicaments à l'étude pour des essais cliniques dans les hôpitaux, dans l'intention d'établir des normes et de trouver des moyens de limiter les coûts qui soient appropriés du point de vue moral.

8.43 Par conséquent, le comité recommande qu'une limite légale de responsabilité soit établie pour l'administration des médicaments, de sorte que les associations et les personnes à leur service soient déchargées, sous des conditions précises, de leur responsabilité quant à l'administration ou la surveillance des médicaments dans les établissements.

8.44 Par conséquent, le comité recommande que des cours portant sur les qualifications requises par les professionnels de la santé pour administrer les médicaments et surveiller l'observance thérapeutique des patients en établissement soient développés et qu'ils soient offerts dans le cadre de programmes d'hygiène publique.

8.45 Par conséquent, le comité recommande que les programmes prévoyant la surveillance de l'observance pharmacothérapeutique des patients et l'administration des médicaments, et les activités de rappel, soient favorisés et financés dans le cadre de programmes de santé communautaire et d'hygiène publique.

8.46 Par conséquent, le comité recommande que les programmes de surveillance de l'observance pharmacothérapeutique soient inclus dans le cadre des programmes approuvés qui sont développés ou mis en oeuvre par les équipes communautaires d'évaluation, les hôpitaux de jour et les centres pour soins de jour.

## Chapitre IX L'utilisation médicamenteuse

9.1 Par conséquent, le comité recommande que les personnes à faibles revenus ou les personnes encourant des frais désastreux en médicaments, qui ne sont pas protégées par des régimes privés d'assurance-maladie, soient défrayées de leurs médicaments par l'entremise d'un régime fondé sur un examen des ressources provenant du revenu, compte tenu d'un ajustement pour le nombre de personnes à charge, conformément aux lignes de conduite de l'aide sociale, et que des co-paiements soient perçus des personnes et des familles dont les revenus dépassent les niveaux d'aide sociale.

9.2 Par conséquent, le comité recommande que les prestataires du Programme de médicaments gratuits de l'Ontario qui ne reçoivent pas d'aide sociale soient tenus de participer aux coûts des ordonnances. Le partage des coûts prendrait la forme d'un montant forfaitaire ne dépassant pas 4 \$, à payer pour chaque ordonnance. Le maximum annuel à payer par le consommateur pour des produits de prescription serait fixé

à 250 \$. Les frais de médicaments au-delà de ce montant seraient complètement couverts par le Programme de médicaments gratuits de l'Ontario.

9.3 Par conséquent, le comité recommande que le ministère de la Santé, conjointement avec le Council of Ontario Faculties of Medicine, entreprenne le développement, d'ici 1992, de programmes pilotes pour la révision de l'utilisation médicamenteuse, qui pourront devenir un élément important de l'éducation médicale permanente. Ces programmes auraient pour objet d'identifier des moyens pratiques et efficaces d'améliorer la qualité de la prescription médicamenteuse et l'état de santé des patients. De tels projets devraient recevoir l'appui financier, à distance, de la province. (Voir aussi la recommandation 4.6.)

9.4 Par conséquent, le comité recommande qu'un programme d'information sur les réactions indésirables aux médicaments en Ontario soit maintenu et qu'il reçoive l'assistance de la province.

9.5 Par conséquent, le comité recommande que les gouvernements du Canada et de l'Ontario, ainsi que les municipalités, mettent sur pied les mécanismes nécessaires, adéquatement financés et soutenus, pour rendre la toxicomanie aussi socialement indésirable.

9.6 Par conséquent, le comité recommande que l'Association des médecins de l'Ontario, le Collège des médecins de famille du Canada et la Fondation de la recherche sur la toxicomanie effectuent conjointement des recherches sur les diverses méthodes pour réduire l'usage excessif des somnifères, des sédatifs et des tranquillisants.

9.7 Que les produits pharmaceutiques et les autres thérapies médicamenteuses indiquées médicalement (comme les enzymes et les vitamines nécessaires) servant au

traitement de la fibrose kystique soient subventionnés au titre du programme pertinent du ministère de la Santé.

9.8 Que les produits pharmaceutiques et autres fournitures médicales servant au traitement de la thalassémie soient subventionnés au titre du programme pertinent du ministère de la Santé.

## Chapitre XI La pharmacothérapie des personnes âgées

11.1 Par conséquent, le comité recommande que le Comité d'appréciation des médicaments et des thérapeutiques soit invité à examiner de façon spécifique la disponibilité de formulations liquides ou autres de certains médicaments, comme le fer et l'acétaminophène, à l'intention des personnes qui ont de la difficulté à avaler ou à prendre des médicaments sous forme solide.

11.2 Par conséquent, le comité recommande que les cartes à mémoire, qui seront offertes pour faciliter l'usage, la surveillance et la révision des médicaments (voir la recommandation 8.10), soient programmées de manière à permettre la détection rapide de problèmes de pharmacothérapie (p. ex. des interactions médicamenteuses). Le système de communication électronique recommandé à toutes les pharmacies (voir la recommandation 8.2) devrait aussi être programmé pour tenir compte des problèmes spéciaux concernant la prescription médicamenteuse aux personnes âgées.

11.3 Par conséquent, le comité recommande que la Direction générale de la protection de la santé du gouvernement fédéral et le Comité d'appréciation des médicaments et des thérapeutiques de l'Ontario :

- a) soient invités à encourager les fabricants à faire en sorte que, lorsque cela est possible et pertinent, les résultats d'essais de médicaments qui accompagnent les demandes de permis et d'inscription incluent des données provenant de personnes âgées, afin que la sûreté et la l'efficacité du médicament puissent être déterminées pour ce groupe. De même, les facultés de médecine ontariennes qui commanditent des essais de médicaments devraient être invitées à inclure des sujets âgés lorsque cela est possible et pertinent; et
- b) soient invités à exiger des fabricants de produits pharmaceutiques qu'ils fournissent des données et des recommandations spécifiques en vue de la prescription aux personnes âgées, lorsque cela est pertinent.

11.4 Par conséquent, le comité recommande que :

- a) Le ministère de la Santé, sur l'avis d'organismes pour les personnes âgées, développe des lignes de conduite et une campagne d'information dans le but d'amener, d'ici 1994, tous les patients, et surtout les personnes âgées, à se choisir un médecin personnel et à ne pas en changer.
- b) L'Association des médecins de l'Ontario, l'Ontario Hospital Association et le College of Physicians and Surgeons of Ontario établissent d'ici 1992 des lignes de conduite pour assurer que les spécialistes et les cliniques d'hôpitaux informent méticuleusement et rapidement le médecin de famille d'un patient de tout changement suggéré à son régime médicamenteux.
- c) Le College of Physicians and Surgeons of Ontario, le Collège des médecins de famille du Canada et l'Association des médecins de l'Ontario établissent, d'ici

1992, des lignes de conduite pour amener les médecins qui dispensent des soins primaires à tenir et à mettre à jour régulièrement une liste des médicaments pris par un patient âgé. Cette information devrait être partagée avec les autres professionnels prenant soin du patient.

- d) L'Association des médecins de l'Ontario et l'Ontario Hospital Association, conjointement avec des organisations pour les personnes âgées, établissent d'ici 1991 des règles de conduite pour communiquer aux médecins la nécessité d'exiger des patients ayant un régime médicamenteux complexe qu'ils apportent avec eux tous leurs médicaments à chaque visite à un médecin ou à l'hôpital.

11.5 Par conséquent, le comité recommande que, d'ici 1992, le College of Physicians and Surgeons of Ontario, le Collège royal des chirurgiens dentistes de l'Ontario et l'Ontario Medical Association élaborent des lignes directrices pour que les ordonnances pour les somnifères, les sédatifs et les tranquillisants soient données pour la période la plus courte possible et que les contenants portent clairement le libellé «sans renouvellement» à moins d'une indication clinique contraire.

11.6 Par conséquent, le comité recommande que toutes les facultés de médecine de l'Ontario soient priées de réviser leurs programmes d'enseignement aux niveaux des premier, deuxième et troisième cycles, d'ici le 1<sup>er</sup> juin 1992, pour s'assurer que :

- a) elles offrent l'enseignement et l'expérience nécessaires pour la prescription de médicaments aux personnes âgées, en soulignant les différences par rapport aux jeunes patients; et
- b) tous les programmes de formation de deuxième et troisième cycles en médecine familiale et dans les spécialités comprennent des rotations spécifiques

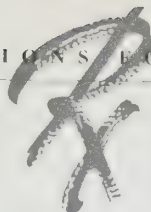


en médecine gériatrique, dont une expérience supervisée en pharmacothérapie, dans des établissements pour soins ambulatoires et de longue durée ainsi que dans des établissements pour soins aigus.

11.7 Par conséquent, le comité recommande que l'Association des médecins de l'Ontario soit invitée à réviser, d'ici le 1<sup>er</sup> janvier 1992, les cours d'éducation permanente offerts aux médecins ontariens, en ce qui concerne tous les aspects de la médecine gériatrique et de la pharmacothérapie pour les personnes âgées, afin de déterminer s'ils sont adéquats. L'Association des médecins de l'Ontario, en collaboration avec les facultés de médecine ontariennes, devrait être invitée à s'assurer que les lacunes sont comblées, de sorte que les médecins ontariens puissent mettre facilement et régulièrement à jour leurs connaissances et leurs compétences concernant les soins aux personnes âgées et la prescription de médicaments pour elles.

11.8 Par conséquent, le comité recommande que le Collège royal des médecins et chirurgiens du Canada et le Collège des médecins de famille du Canada soient invités à réviser leurs objectifs en éducation et leurs exigences concernant l'enseignement médical en gériatrie et la pharmacothérapie des personnes âgées.

11.9 Par conséquent, le comité recommande que le ministère de la Santé, conjointement avec l'Ontario Hospital Association, l'Ontario Association of Non Profit Homes and Services for Seniors et l'Association des maisons de soins infirmiers de l'Ontario, exige que, d'ici le 1<sup>er</sup> juillet 1992, tous les hôpitaux pour soins aigus et les établissements pour soins gériatriques de longue durée mettent sur pied des systèmes pertinents pour surveiller la pharmacothérapie des patients âgés.



## Annex I

### Committee Members and Inquiry Staff

#### Chairman:

##### Frederick H. Lowy

Dr. Frederick Lowy, dean of medicine at the University of Toronto from 1980 to 1987, is a professor of psychiatry at that university. In June 1989 Dr. Lowy was appointed the first director of the University of Toronto's new centre for bioethics. A medical graduate of McGill University (1959), Dr. Lowy interned and began residency training in internal medicine at the Royal Victoria Hospital, Montreal. After a period of general practice he undertook psychiatric training at the University of Cincinnati. He returned to Canada to join the staff of the Allan Memorial Institute and the department of psychiatry, McGill University, in 1965.

In 1970 Dr. Lowy became chief of psychiatry at the Ottawa Civic Hospital. In 1974 he moved to Toronto to take up the positions of director and psychiatrist-in-chief at the Clarke Institute and chairman of the department of psychiatry, University of Toronto. He held these positions until he became dean of the faculty of medicine in 1980.

#### Committee:

##### Martha Jordan

Martha Jordan, R.N., is staff development coordinator at Rideaucrest Home in Kingston, Ontario. Prior to assuming this position, she worked in various roles in the home, where she evaluated and implemented an up-to-date medication administration system.

Mrs. Jordan was graduated from the Royal Victoria Hospital School of Nursing, Montreal in 1968. Following this she assumed positions at the Toronto Western Hospital and Rockyview Hospital, Calgary, in coronary care, emergency and intensive care.

She holds certificates in gerontological nursing and health care unit administration from St. Lawrence College, Kingston.

Mrs. Jordan is a member of the Ontario Nurses' Association, the Registered Nurses' Association of Ontario, and the Gerontological Nursing Association of Ontario.

## Michael Gordon

Dr. Michael Gordon was born in New York City and received his undergraduate degree from Brooklyn College. He completed medical school training at the University of St. Andrews in Scotland and proceeded to do intern training at the Aberdeen City Hospital, Scotland, Rambam Hospital, Haifa, Israel and Boston University Hospital.

His residency training took place at the Royal Victoria Hospital, Montreal, the Hadassah and Shaare Sedek hospitals in Jerusalem and the Toronto General and Mount Sinai hospitals in Toronto. Dr. Gordon is currently medical director of the Baycrest Centre for Geriatric Care, head of the division of geriatrics at Mount Sinai Hospital and associate professor of medicine at the University of Toronto. He is married and has four children.

## Richard Moulton

Dr. Richard Moulton is a family physician and educator of family physicians from Fort Frances in rural Northern Ontario where he has lived for 25 years. He was educated in England at Cambridge and London and early on became interested in pharmacology: co-authoring (with D.R. Laurence) the first edition of "Clinical Pharmacology." He moved from academic medicine to family practice and then emigrated to Canada.

He has always been interested and involved in health care planning, medical education and therapeutics. He was a founding member of the Kenora-Rainy River District Health Council and a past-president of the Canadian Association of Medical Clinics.

He is currently associate professor of family medicine, University of Western Ontario; board member, Ontario Medical Association; a partner in the Fort Frances Clinic and an active staff member at La Verendrye Hospital, Fort Frances. He is a member and past-chairman of the Ontario Medical Association committee on drugs and pharmacotherapy. The committee runs the adverse drug reaction program and provides "The Drug Report."

## Reva Spunt

Reva Spunt, M.S.W., is a medical social worker with a specific interest in the needs of the elderly. Though her employment ranged from immigration and vocational counselling, to medical and social work, her clientele was always predominantly in the older age group.

As coordinator of gerontological services at North York General Hospital she was instrumental in developing programs to serve the needs of the elderly both in hospital and in the community. A day care centre for the frail elderly, an outpatient seniors' assessment service and the seniors' committee of the North York Inter-Agency Council are among the services in place today that were initiated by Mrs. Spunt.

Her private practice, "Seniors' Resource and Consultation Services," now allows Mrs. Spunt to be totally available to elders, their families and institutions on a personal level, through training of staff, and providing lectures and workshops.



## **Jake J. Thiessen**

Jake J. Thiessen, Ph.D. is a pharmacist who gained his professional degree from the University of Manitoba. After completing the M.Sc. degree at the same university, he obtained his doctoral degree from the University of California, San Francisco, specializing in the field of pharmacokinetics.

Dr. Thiessen is currently professor and coordinator of the graduate department in the faculty of pharmacy, University of Toronto. Over the past 17 years his teaching responsibilities have included both undergraduate and graduate pharmacokinetics. As part of his research activities he has supervised numerous graduate students at both the masters and doctoral levels. His independent and collaborative research, funded primarily by organizations like the Canadian Medical Research Council, has examined theoretical pharmacokinetic concepts and practical issues in clinical pharmacotherapy.

Dr. Thiessen has participated in a variety of extra-university activities including teaching assignments in Africa and the Caribbean. He has contributed to the profession of pharmacy as chairman of the Canadian Hospital Pharmacy Residency Board. Dr. Thiessen currently serves the Ontario Minister of Health as chairman of the Drug Quality and Therapeutics Committee.

## **Donald C. Webster**

Donald C. Webster, born in 1930, was raised in Montreal where he attended Lower Canada College. Mr. Webster was graduated with a B.Sc. in mechanical engineering from Princeton University (1951) and attended the Centre d'Etudes Industrielles (1953) in Geneva, Switzerland. Between 1951 and 1956, he held engineering positions with Dominion Engineering Works, CIL, Dupont Canada and Liquifuels Limited. He

subsequently embarked upon various venture activities, and is a co-founder of Velcro Industries, Harvey's Foods and Neptune Terminals.

From 1968 to the present he has been chairman of Helix Investments Limited, a venture capital company he co-founded in 1968 and which currently has assets in excess of \$120 million.

Mr. Webster is a past director of the National Research Council of Canada and the Royal Ontario Museum. He is currently chairman of Geac Computer Corporation Limited and a director of the following public companies: Anthes Industries Inc., Corel Systems, Helix Circuits Inc., Hyal Pharmaceutical Ltd.; of the following private companies: Canadian General Investments Ltd., Cast Marine Holdings, Interactive Entertainment Inc., Rieder Distillery Ltd., Tolerant Systems Inc., Walker Interactive Inc., Webber Pharmaceuticals Ltd.; and of the following non-profit organizations: Canadian Schizophrenic Foundation and Canadian Psychiatric Research Foundation.

Mr. Webster is a member of the Premier's Council of Ontario.

## **William Robert Wensley**

Bill Wensley is registrar of the Ontario College of Pharmacists, the licencing and regulating body for pharmacy in Ontario. The college is set up under authority of the Ontario Health Disciplines Act and as chief executive officer, Mr. Wensley is responsible for ensuring that suitable procedures are in place and carried out to administer the legislation. The college is involved in many activities, including the licencing of pharmacists, continuing education and drug information as well as accreditation of pharmacies, pharmacy inspections and the general administration of the laws in Ontario regarding the sale of drugs by retail.

Mr. Wensley is a graduate of the faculty of pharmacy, University of Toronto, and holds a masters degree in pharmaceutical manufacturing and business administration, also from the University of Toronto. His experience includes community pharmacy, manufacturing pharmacy, university teaching and pharmacy administration.

He is a former member of the Ontario Council of Health and the Drug Quality and Therapeutics Committee, which are advisory bodies to the Minister of Health. Mr. Wensley has also served on many other university, provincial and federal government committees and boards, including the Senate of the University of Toronto, human resource advisory committees and drug security studies.

## **Executive Director:**

### **Wendy Kennedy**

Ms. Kennedy currently works with the Canadian Public Health Association as project director for the national advisory panel on risk/benefit management of drugs. She has been involved in various aspects of the pharmaceutical industry since 1983: with government through the Eastman Commission and Idea Corporation, and in private industry with Novopharm Limited. Before obtaining her MBA from York University, she practiced law in Alberta, both in general private practice and as corporate in-house counsel. She was graduated from the faculty of law at the University of Alberta in 1975.

## **Director of Research:**

### **J. Ivan Williams**

Jack Williams, research director, is the deputy director of the clinical epidemiology unit at Sunnybrook Health Science centre and professor in the departments of family and community medicine and preventive medicine and biostatistics at the University of Toronto.

After completing his Ph.D. in sociology at Florida State University, he held teaching positions at the universities of Western Ontario and Toronto. He started and directed health care research units at both universities.

Prior to moving to this present position, he was a professor in the department of epidemiology and biostatistics at McGill University and a member of the division of clinical epidemiology at Montreal General Hospital. His research interests include the evaluation of prehospital emergency services, quality of care in family practice, and methods for assessing the quality of life. He has held a number of research grants and has published articles in peer-reviewed journals.



## Annex II

### Alphabetical List of Briefs/Presentations

*The following, in alphabetical order, is the list of briefs and presentations made to the Inquiry.  
Copies of all briefs are maintained on file with the Ministry of Health of Ontario,  
and information about obtaining copies should be directed to the  
drug programs branch of the MOH.*

Abbott Pharmaceuticals, Ross Laboratories  
Division—176  
Montreal, Quebec

Adamson, Neil, Adamson Guardian Drugs  
—179  
Wheatley, Ontario

Addiction Research Foundation—73  
Toronto, Ontario

Advocacy Resource Centre for the  
Handicapped—130  
Toronto, Ontario

Alzheimer's Society—98  
Thunder Bay, Ontario

Amethyst Women's Addiction Centre—120  
Ottawa, Ontario

Anonymous—21

Apotex Inc.—62  
Weston, Ontario

Association of Chief Pharmacists of Ontario  
Psychiatric Hospitals—188  
Toronto, Ontario

Association of Jewish Seniors—59  
North York, Ontario

Astra Pharma Inc.—80  
Mississauga, Ontario

Ayerst Laboratories—67  
Saint-Laurent, Quebec

Baker, Margaret—6  
Ottawa, Ontario

Bardeggia, Aldo—135  
Toronto, Ontario

Bayshore Pharmacy Ltd.—32  
Ottawa, Ontario

Bertin, Leonard—30  
Toronto, Ontario

Bertram, James—145  
Thunder Bay, Ontario

Big V Pharmacies Co. Limited—144  
London, Ontario

Board of Trade of Metropolitan Toronto (The)  
—172  
Toronto, Ontario

Boehringer Ingleheim (Canada) Ltd.—113  
Burlington, Ontario

Brant District Health Council—29  
Brantford, Ontario



Bumstead, James W./D.Joyce—158  
Owen Sound, Ontario

Canadian Dermatology Association—27  
Kingston, Ontario

Canadian Diabetes Association, Ontario  
Division—86  
London, Ontario

Canadian Drug Manufacturers  
Association—53  
Downsview, Ontario

Canadian Holistic Medical Association—92  
Toronto, Ontario

Canadian Pharmaceutical Association—170  
Ottawa, Ontario

Canadian Society of Hospital Pharmacists,  
Ontario Branch—69  
Markham, Ontario

Canadian Wholesale Drug Manufacturers  
Association—2  
Montreal, Quebec

Cascagnette, Mary—19  
Midland, Ontario

Chambers, Marie J.—187  
Toronto, Ontario

Chan, Jeff—100  
Thunder Bay, Ontario

Chiles, Vernon K.—65  
Sarnia, Ontario

Chow, Edwin, The Village Pharmacy—177  
Petawawa, Ontario

City of Toronto, Department of Public Health  
—166  
Toronto, Ontario

College of Family Physicians of Canada,  
Ontario Chapter—54  
Willowdale, Ontario

College of Nurses of Ontario—107  
Toronto, Ontario

Community Occupational Therapy  
Associates—17  
Toronto, Ontario

Connor, John T., Casselman Pharmacy Ltd.  
—123  
Casselman, Ontario

Consumers Association of Canada (Ontario)  
—55  
Toronto, Ontario

Council for Accreditation of Pharmaceutical  
Manufacturers Representatives of Canada  
—121  
St. Laurent, Quebec

Council of Ontario Faculties of Medicine—52  
Toronto, Ontario

Council on Aging of Ottawa-Carleton—118  
Ottawa, Ontario

Council on Positive Aging Thunder Bay,  
Steering Committee—97  
Thunder Bay, Ontario

Cystic Fibrosis Foundation, Cornwall Chapter  
—23  
Cornwall, Ontario

Cystic Fibrosis Chapter of Thunder Bay—139  
Thunder Bay, Ontario

Cystic Fibrosis Foundation—15  
Toronto, Ontario

Daoust, Pierre—143  
Ottawa, Ontario

- |  |  |
|--|--|
| Davidson, Alan S.—48<br>Bracebridge, Ontario                       | Genentech Canada Inc.—148<br>Burlington, Ontario   |
| Derrett, Greg—5<br>Guelph, Ontario                                 | Geraldton Elderly Person's Centre—82<br>Geraldton, Ontario   |
| Drug Trading Company Limited—31<br>Scarborough, Ontario            | Gerontology Research Council of Ontario—66<br>Hamilton, Ontario  |
| Drug Trading Co. Ltd., Kitchener—34<br>Kitchener, Ontario          | Gibson, Margaret—10<br>Cobourg, Ontario  |
| Durham Regional Pharmacists Association<br>—132<br>Oshawa, Ontario | Glaxo Canada Inc.—42<br>Toronto, Ontario   |
| East End Health Services—45<br>Toronto, Ontario                    | Gordon, J.R.M. and C. Maule—16<br>Kingston, Ontario  |
| Eli Lilly Canada Inc.—111<br>Scarborough, Ontario                  | Gormley, Helen—105<br>Oshawa, Ontario  |
| Elliot, Jean—126<br>Guelph, Ontario                                | Green Shield Prepaid Services Inc.—103<br>Willowdale, Ontario  |
| English, Robert L.—14<br>Fergus, Ontario                           | Haldiman-Norfolk District Health Council—39<br>Townsend, Ontario   |
| Epilepsy Association, Metro Toronto—169<br>Toronto, Ontario        | Hall, Larry and Lillian—185<br>Pickering, Ontario  |
| Epp, Ernie, M.P., Thunder Bay/Nipigon—99<br>Thunder Bay, Ontario   | Hamilton and District Pharmacists Association<br>—85<br>Hamilton, Ontario                                |
| Essex County Pharmacists Association—87<br>Windsor, Ontario        | Harris, Leanne, Valley Pharmacies/Carleton<br>Place Drug Mart—112<br>Smith Falls, Ontario                |
| Faibish, Sydney, Fieldgate Pharmacy —181<br>Mississauga, Ontario   | Hartman, Joy A.—26<br>Thunder Bay, Ontario   |
| Fleming, Kevin, Shoppers Drug Mart—180<br>Cambridge, Ontario       | Health and Welfare Canada, Health Protection<br>Branch, Bureau of Dangerous Drugs—171<br>Ottawa, Ontario |
| Flint Laboratories (Canada) Ltd.—174<br>Etobicoke, Ontario         | Hemple, Donald G.—64<br>Woodstock, Ontario   |

Hill, John—74  
Brantford, Ontario

Homewood Sanitarium—93  
Guelph, Ontario

Income Maintenance for the Handicapped  
Coordinating Group—46  
Toronto, Ontario

Huron Lodge Home for the Aged—83  
Windsor, Ontario

Inter-University Group on Drug Utilization  
—41  
Montreal, Quebec

Jackson, Barbara—68  
Toronto, Ontario

Jechel, Klaus W.—140  
Kingston, Ontario

Jones, J.E.—4  
Orleans, Ontario

Jutzi, Helen—22  
Kitchener, Ontario

Kent County Pharmacist Association—88  
Chatham, Ontario

Kidney Foundation of Canada (The)—153  
Toronto, Ontario

Kiwanis Club of Ottawa Inc.—116  
Ottawa, Ontario

Lamont, James R.—7  
Scarborough, Ontario

Livingston Pharmaceutical Distribution Ltd.  
—164  
Etobicoke, Ontario

MacLeod, S.M.—79  
Hamilton, Ontario

Manitoulin-Sudbury DHC, Seniors Long Term  
Care—137  
Sudbury, Ontario

Manitoulin-Sudbury DHC, Mental Health  
Committee—134  
Sudbury, Ontario

Martin, Gordon K.—20  
North York, Ontario

McGuire, Brian and Maria—151  
Ottawa, Ontario

McLay, Dennis—136  
Copper Cliff, Ontario

Medical Reform Group of Ontario—40  
Toronto, Ontario

Meloff, Keith Lyon—1  
Toronto, Ontario

Merck Frosst Canada Incorporated—141  
Point Claire-Dorval, Quebec

Metro Toronto District Health Council – 167  
Toronto, Ontario

Metropolitan Toronto Police—154  
Toronto, Ontario

Ministry of Community and Social Services,  
Income Maintenance Branch—109  
Toronto, Ontario

Monsour, Nick—133  
Sarnia, Ontario

Municipality of Metro Toronto, Office of the  
Chairman, Economic Development Division  
—168  
Toronto, Ontario

Musial & Taciuk Associates—127  
Islington, Ontario



Myncet Canada—60  
Toronto, Ontario

Niagara District Health Council—108  
Fonthill, Ontario

Nordic Laboratories Inc.—189  
(Confidential)

North York Inter-Agency and Community  
Council, Seniors' Services Committee—104  
North York, Ontario

Northcott, Helen—90  
Chatham, Ontario

Novopharm Ltd.—61  
Scarborough, Ontario

Ombricolo, Angela—13  
Downsview, Ontario

Ontario Advisory Council on Women's Issues  
—163  
Toronto, Ontario

Ontario Cancer Treatment and Research  
Foundation (OCTRF)—184  
Toronto, Ontario

Ontario Coalition of Senior Citizens'  
Organizations—76  
North York, Ontario

Ontario College of Pharmacists—119  
Toronto, Ontario

Ontario Hospital Association—57  
Don Mills, Ontario

Ontario Medical Association—115  
Toronto, Ontario

Ontario Ministry of Community and Social  
Services, Community Services Division—37  
Toronto, Ontario

Ontario Ministry of Health, Drug Programs  
Branch—36  
Toronto, Ontario

Ontario Nurses Association—35  
Toronto, Ontario

Ontario Nursing Homes Association—75  
Willowdale, Ontario

Ontario Pharmacists' Association—43  
Toronto, Ontario

Ontario Provincial Police, Ministry of the  
Solicitor General—162  
Toronto, Ontario

Ontario Public Service Employees Union—78  
Toronto, Ontario

Ottawa Advocates for Psychiatric Patients  
—122  
Ottawa, Ontario

Ottawa-Carleton Pharmacy Association—142  
Ottawa, Ontario

Pharmaceutical Manufacturers Association of  
Canada—114  
Ottawa, Ontario

Pangman, Constance—33  
Mississauga, Ontario

Parke-Davis Canada Inc.—182  
Scarborough, Ontario

Patients Rights Association—56  
Toronto, Ontario

Pfizer Canada Inc.—146  
Pointe-Claire, Quebec

Pharmaceutical Advertising Advisory Board  
—72  
Pickering, Ontario

Phoenix Risin—51  
Toronto, Ontario

Pine Ridge Pharmacists Association—106  
Cobourg, Ontario

Pollard Pharmacy of Parry Sound Ltd.—175  
Parry Sound, Ontario

Powell, Robert C.—9  
Port Hope, Ontario

Psychiatric Patient Advocate Office—63  
Toronto, Ontario

PUSH Ontario—131  
Toronto, Ontario

RAISE Home Support for Elderly—28  
Kitchener, Ontario

Ray, A.K.—11  
Gloucester, Ontario

Reich, Carl—155  
Calgary, Alberta

Rho Pi Phi International Fraternity, Rokeah  
Chapter —47  
Downsview, Ontario

Rhone-Poulenc Pharma Inc.—24  
Whitby, Ontario

Rideau Valley District Health Council—149  
Smith Falls, Ontario

Rideout, Adrienne—18  
Burlington, Ontario

Riepart, R.—125  
Kitchener, Ontario

Roe, T.F., Thomas Roe Shoppers Drug Mart  
—159  
Don Mills, Ontario

Rogers Pharmaceuticals—84  
Toronto, Ontario

Royal Canadian Mounted Police  
(The Commissioner)—161  
Ottawa, Ontario

Rumball, John—50  
Toronto, Ontario

Ryan, Ann—8  
Amherstburg, Ontario

Sandoz Canada Inc.—102  
Dorval, Quebec

Sault Ste. Marie Pharmacists' Association  
—101  
Sault Ste. Marie, Ontario

Schramm, Ursula—156  
Hawkestone, Ontario

Searle Canada Inc.—147  
Oakville, Ontario

Shoppers Drug Mart Limited—117  
Willowdale, Ontario

Sims, G.—3  
Windsor, Ontario

Sinclair, John—183  
Stratford, Ontario

Smith Kline & French Canada Ltd.—58  
Mississauga, Ontario

Society of Independent Community  
Pharmacists—129  
Islington, Ontario

Spence, J.W., Wishing Well Pharmacy—178  
Agincourt, Ontario

St. Joseph's General Hospital—81  
Thunder Bay, Ontario

St. Thomas-Elgin General Hospital—157  
St. Thomas, Ontario

Stonehenge Therapeutic Community—77  
Guelph, Ontario

Strader, Nelson J., Wexford Heights Pharmacy  
—186  
Scarborough, Ontario

Sudbury Acute Care Hospitals (Laurentian,  
Sudbury General and Sudbury Memorial)—94  
Sudbury, Ontario

Sudbury and District Pharmacists' Association  
—95  
Sudbury, Ontario

Superannuated Teachers of Ontario—38  
Toronto, Ontario

Szul, Michael—12  
Toronto, Ontario

The Honorable Mavis Wilson, Minister  
Responsible for Senior Citizens Affairs—71  
Toronto, Ontario

Thompson-Guppy, Airdrie—152  
Ottawa, Ontario

Thunder Bay and District Health Coalition  
—96  
Thunder Bay, Ontario

Thunder Bay Medical Society—150  
Thunder Bay, Ontario

Thunder Bay Pharmacists Association—138  
Thunder Bay, Ontario

Tomlinson, P.A.—25  
Port Hope, Ontario

Treste, Mr.—128  
Toronto, Ontario

United Pharmacists Wholesale Manitoba  
Ltd.—44  
Winnipeg, Manitoba

University of Toronto, Faculty of Medicine  
—173  
Toronto, Ontario

University of Ottawa, Faculty of Health  
Sciences—165  
Ottawa, Ontario

University of Toronto, Faculty of Pharmacy  
—49  
Toronto, Ontario

University of Western Ontario, Health Science  
Centre—110  
London, Ontario

Upjohn Company of Canada—70  
Don Mills, Ontario

Van Den Spiegel, Stella—89  
Chatham, Ontario

VON for Canada, Health Promotion Project  
—91  
Smith Falls, Ontario

Wellington-Dufferin District Health Council  
—124  
Guelph, Ontario

Willison, Donald—160  
Dundas, Ontario







## Index

- Abuse 159, 163, 165
- Access 1, 6, 8, 11, 13, 17, 27, 28, 74, 116, 128, 142, 150, 156, 172
- Actual Acquisition Cost (AAC) 18, 28, 31, 82
- Addiction Research Foundation (ARF) 163, 169
- Adverse drug interaction 123
- Adverse drug reaction(s) 5, 57, 103, 161, 181, 186, 189,
- Adverse drug reporting 93
- Adverse effects; adverse reactions 116, 132, 157
- Advertising 16, 68, 105, 111-112, 159
- Affordable; affordability 5, 8, 11-12
- Alberta 28, 168
- Auxiliary personnel (see also Pharmacy assistants) 121
  
- BAP (Best Available Price) 19, 20, 29, 39, 40, 55, 62, 64, 69, 70, 78, 80, 82
- Benefit(s) 10, 35-36, 40, 117, 173
- Benefit/cost 10
- Benefit/risk 10
- Best Available Price (see BAP)
- Bill C-22 57, 66
- Bill 54/55 (See also Ontario Drug Benefit Act; Prescription Drug Cost Regulation Act) 19, 61
- Bio-availability 39, 46, 48
- Bioequivalence 37, 46, 57
- Blue Cross (see also Ontario Blue Cross) 13, 27, 75, 150
- Brand-name 52, 57, 64, 76
- British Columbia 28, 53, 155, 170, 171
- Bureau of Dangerous Drugs 166
  
- Canada Health Act 8, 11, 14
- Canada Health Promotion Survey 164
- Canada Health Survey 143-144, 157
- Canadian Society of Hospital Pharmacists-Ontario Branch (CSHP) 114, 119, 134-135
- Canadian Drug Manufacturers' Association (CDMA) 49, 53, 106
- Canadian Medical Association (CMA) 16
- Canadian Pharmaceutical Association 106
- Canadian Wholesale Drug Manufacturers Association (CWDMA) 20, 79, 81, 83
- Capitation fee 170
- Carecor 54
- Catastrophic drug costs 27, 153
- CDI (see also Comparative Drug Index) 15-18, 20
- Choice of Medications 35, 105-106, 108, 132
- Chronic care 8, 170
- Chronic drug costs (See also 'catastrophic drug costs') 10
- Clinical pharmacologist(s) 108
- Clinical pharmacology 102, 113
- Clinical drug trials 46, 55, 136, 176, 178-179, 184
- Co-payment(s) 31, 11, 28, 36, 39, 75, 151, 154
- College of Physicians and Surgeons of Ontario 39, 98, 106-107, 111
- College of Family Practice 96, 107
- College of Nurses of Ontario 133, 169
- Communication 125
- Community Occupational Therapy Association (COTA) (see also Occupational therapists 138)
- Comparative Drug Index (CDI) 15-18, 20
- Compendium of Pharmaceuticals and Specialties (CPS) 108, 132, 159
- Compliance 95, 110, 124-126, 132, 136, 160, 181, 187
- Comprehensive Health Organization(s) (CHO) 109, 127
- Compulsory licence(s) 52, 57, 61, 67
- Computers 121
- Consent for treatment 96
- Consumer(s) 8-9, 12, 47, 69, 93, 117, 120, 124, 141, 156-158, 165, 175
- Continuing education 132-133, 178
- Continuing medical education 104-105, 122, 188

- Correctional institutions 8
- Cost 5, 8-9, 95
- Cost-benefit 10, 42, 103, 105
- Cost containment; cost control 12, 29, 136
- Cost-effective; cost-effectiveness 1, 2, 8, 12, 37, 42, 44, 90, 103, 111, 115, 160
- Cost-sharing 23-24
- Council of Faculties of Medicine (COFM) 39, 103, 113, 131
- Council of Ontario Universities' Health Science Faculties 131
- Counselling 130, 132, 184
- CPI (Consumer Price Index) 58-60, 69-70, 148
- Cystic fibrosis 135, 153, 173
  
- Dentist(s) 10, 36, 93
- Dentistry 8
- Disability; disabled 143, 146-147, 152, 183
- Disease(s) 6, 55, 92, 94-95, 110, 178
- Dispense as written 20
- Dispensing fee 16, 19, 29, 31, 82, 98, 121, 149, 156, 170
- Dispensing limit 19
- Distribution agreement 83
- Doctor of Pharmacy 130
- Double doctoring 167
- DQTC (Drug Quality and Therapeutics Committee) 9, 15, 20, 38, 48, 64, 69, 71, 86, 106, 108, 118, 182
- Drug abuse (see abuse)
- Drug cost(s) 11, 14, 26, 29, 76
- Drug detailing 111
- Drug distribution 122
- Drug interaction(s) 68, 103, 116, 121, 181, 189
- Drug prices 75
- Drug testing laboratory 15
- Drug Trading 81
- Drug utilization 34, 101, 112, 183, 189
- Drug utilization review 31, 34, 37, 42, 93, 120, 132, 183
  
- Eastman report 65-66
- Economic benefits 64
- Economical pharmacotherapy 108
- Education 102, 117, 120, 124, 128, 133, 143, 159, 168, 176, 180, 186
  
- Effectiveness 17
- Elderly 34, 94, 103, 116, 120, 139, 146-147, 163, 165, 168, 188
- Eligibility 2
- Emergency drug release 55
- Established programs financing 24
- Extended care 8, 24, 148, 169
  
- Family benefits 8, 13, 24, 27, 148, 151
- Financial barriers 13
- Food and Drugs Act 46
- Formulary 28-29, 34-35, 37, 39, 42-43, 57-58, 60-61, 69-70, 106, 108, 114, 121, 189
- France 66
  
- GAINS 17
- Gatekeeper 97
- General welfare 8, 13, 24, 27, 148, 151
- General Welfare Act 13
- Generic 20, 34, 44, 46, 58, 109
- Generic manufacturer(s) 18, 61, 54, 64
- Generic manufacturing 16
- Generic product(s) 15, 36, 48, 57, 65, 71
- Geriatric 104, 187-188
- Geriatric pharmacology 188
- Gerontology Research Council of Ontario 184
- Government pharmacy (see also OGPMS) 169
- Green Shield 14, 27, 74, 79, 150
- Gross provincial product 5
- Guidelines 40, 73, 107, 123
  
- Hall Commission (Royal Commission on Health Services) 10, 14
- Health and Welfare Canada 106, 143
- Health Disciplines Act 170
- Health maintenance organization (HMO) 109
- Health Professions Legislation Review 180
- Health promotion 175
- Health Protection Branch (HPB) 9, 20, 35, 36, 41, 46, 55, 61, 123, 184
- Health status 2, 12, 24, 143, 146, 161
- Home care 8, 25, 136, 148, 175
- Homemakers 139
- Homes for the aged 74, 86, 127
- Hospital(s) 8, 79, 89, 113, 127, 143, 186, 188
- Hospital formulary 73, 115, 134



- Hospital Insurance and Diagnostic Services Act 13
- Hospital pharmacists 77
- Hospital Purchasing Inc. (HPI) 54, 72
- Hospital purchasing plans 115
- Hospital Purchasing Program (HPP) 54, 71-72, 87
- Hospital services 5
- Human resources 122, 128, 131
  
- Industrial products price index 59
- Informed consent 173
- Innovative 46
- Insurance 8, 10
- Interactions (see also drug interaction) 68, 103, 116, 121, 181, 189
- Interchangeable; Interchangeability 9, 15-17, 19-20, 24, 29, 35, 39, 42, 49, 57, 61, 63, 93, 123, 161
- Interim reports 3, 119
- Internships 104
  
- Legislation 9, 12, 16-17, 20, 34-44, 48-49, 51, 65, 66, 71, 112
- Licensing 9
- Limited use 37, 40, 42-43, 45
- Livingston Pharmaceutical Distribution Ltd. 81
- Long term care 137
  
- Manitoba 28, 170, 171
- Marketing 51, 68, 123
- Medical education 100, 112, 183, 188
- Medical Reform Group 92
- Medicine 8
- Ministry of Colleges and Universities 113, 130
- Ministry of Community and Social Services 26-27, 153, 174
- Ministry of Industry, Trade and Technology 40
- Modified release dosage forms 39
- Multiple-source products 17, 35, 64, 67, 80
  
- New Brunswick 13, 28, 31
- Newfoundland 28
- No substitution 39, 47-48, 62, 64
- Non-formulary benefits 46
- Non-prescribed drugs; Non-prescription drugs 124, 126, 144, 148, 158, 183
- Non-proprietary (see also generic) 109
- Northwest Territories 28, 155
- Notice of compliance 37
- Nova Scotia 13, 28, 158, 170
- Nurse(s); nursing 8, 10, 45, 97, 108, 132, 134, 139, 169
- Nursing home(s) 74, 86, 127
- Nutrition 7, 175
- Nutritional pharmacology 176
- Nutritional products 176
- Nutritional supplements 157, 173
  
- Occupational therapists 136
- ODB expenditures 24
- ODB formulary 9, 20, 25, 33, 87, 156, 182
- ODB plan 10, 25, 40, 42, 54, 117, 118, 121, 127, 135, 148
- ODB program 2, 5, 13, 17-18, 31, 43, 63, 79, 98, 144
- OGPMSS (see also Government Pharmacy) 15, 24, 85
- Ontario Assoc of Non-Profit Homes and Services for Seniors 128
- Ontario Blue Cross (see Blue Cross) 13
- Ontario Branch—Canadian Society of Hospital Pharmacists (see Canadian Society of Hospital Pharmacists) 135
- Ontario College of Pharmacists (OCP) 48, 83, 99, 111, 122, 125-126, 134, 169
- Ontario Drug Benefit Act (Bill 54) 18, 34, 39, 41, 43, 79
- Ontario Hospital Association (OHA) 34, 54, 71, 83, 87, 109, 119, 123, 134, 135
- Ontario Medical Association (OMA) 39, 47, 96, 98, 105, 111, 160, 169, 180, 183
- Ontario Nursing Home Association (ONHA) 128, 169
- Ontario Pharmacists Association (OPA) 19, 20, 81, 99, 109, 114, 119, 123, 125-126
- Optimal drug therapy 5, 34, 91, 96, 102, 127, 174
- Optimal pharmacotherapy 11, 37, 185
- Original pack 123
- Outcome review 106
- Over-the-counter 114, 163

- PARCOST 15-16, 33  
 Patent(s) 51, 66-67, 179  
 Patent Act 16  
 Patent legislation 52, 69  
 Patented Medicines Prices Review Board (PMPRB) 53, 58  
 Paternalism 96  
 Patient(s) 97-98, 157  
 Patient education 114, 134  
 Patient profiles 124, 134  
 Pharmaceutical industry 6, 10, 20, 33, 35, 51, 64, 66, 96, 100, 111  
 Pharmaceutical manufacturers 2, 9, 15, 41, 108  
 Pharmaceutical Manufacturers Association of Canada (PMAC) 16, 20, 53, 82, 102  
 Pharmaceutical representatives 105, 111  
 Pharmaceutical research 59  
 Pharmacist(s) 10, 19, 35, 45, 49, 54, 67, 97, 106, 108, 120, 134, 154  
 Pharmaco-economic factors 40, 42  
 Pharmacologists 108  
 Pharmacology 6, 9  
 Pharmacotherapy 6, 8, 10, 11, 12, 33, 38, 39, 47  
 Pharmacy Act 16, 48  
 Pharmacy assistants 121, 132  
 Physician(s) 10, 36, 48-49, 59, 67, 98, 105, 108, 120, 154, 169, 175  
 Physician prescribing 69  
 Physician services 5  
 Pilot projects 12, 171  
 Polypharmacy 189  
 Post marketing evaluation 112  
 Practice standards (see also Standards of practice) 125  
 Premier's Council on Health Strategy 2, 175  
 Prescriber(s) 35, 37, 43, 45, 92-93, 102, 106, 112, 116, 125, 130  
 Prescription Drug Cost Regulation Act (Bill 55) 18, 34, 39, 41, 49, 69, 79  
 Prescription drug market 21  
 Price spreading 18  
 Prince Edward Island 28, 170  
 Product monograph 56  
 Product review 40-41  
 Product selection 17, 29, 31, 39, 44, 47, 76  
 Professional associations 10  
 Professional fees 126  
 Psychiatric hospitals 24, 86, 173  
 Psychotropic(s); psychotropic drugs 164, 174, 189  
 Public education 10, 113  
 Public hearings 2-3  
 PYLL (Potential Years of Life Lost) 142  
 QUAD 17  
 Quality assurance 2, 170  
 Quality control 73  
 Quality of care 2  
 Quebec 28, 53, 59  
 Rational pharmacotherapy 93, 96, 106, 109, 112, 131, 133, 183  
 Rational prescribing 38  
 Rational use 5, 10  
 Rationing 97  
 Regular use 44  
 Regulations 10, 12, 49, 59  
 Restricted use 108, 118  
 Risk 8, 95, 97  
 Risk/benefit/cost 37, 163  
 Royal College of Dental Surgeons of Ontario 39  
 Royal College of Physicians and Surgeons 96, 107  
 Royal Commission on Health Services (See Hall Commission)  
 Safety and efficacy 9, 51, 72, 86, 114  
 Saskatchewan 28, 155  
 Self medication 116  
 Seniors 31, 124  
 Single-source; single source product(s) 35, 67, 70, 80, 173  
 Smart Card(s) 31, 110, 121, 125, 184  
 Social assistance 11, 152  
 Social Assistance Review Committee (SARC) 27, 153  
 Special authorization(s) 20, 26, 37, 43, 108  
 Standards of practice 123  
 Substitution 162

Task Force on the Use and Provision of Medical Services 115  
 Teaching hospitals 103  
 Terms of reference 2, 41  
 Thalassemia 24, 135, 153, 173  
 Third party insurance 68, 127  
 Third party payor; third party insurers 27, 82, 98

Unit dose 89, 121, 123, 132  
 United Kingdom 66  
 United States 66  
 Universal 28  
 Universality 11  
 University of Toronto 129, 131, 134  
 Utilization 2, 14, 26-27, 70, 75, 121, 167

Vaccines 7, 86

West Germany 66  
 Wholesale 54  
 Wholesale distribution companies 78  
 Wholesale distributor 80  
 Wholesale drug distribution 77  
 Wholesaler(s) 19-20, 72, 83  
 Working poor 27-28  
 World Health Organization (WHO) 92, 184

Yukon 28, 155



















